

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

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IN RE: NATIONAL PRESCRIPTION MDL No. 2804  
OPIATE LITIGATION

Case No. 17-md-2804

Judge Dan Aaron

This Document Relates To: Polster

The County of Lake, Ohio v.  
Purdue Pharma L.P., et al.  
Case No. 18-op-45032

The County of Trumbull, Ohio v.  
Purdue Pharma L.P., et al.,  
Case No. 18-op-45079

Track 3 Cases

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Remote videotaped deposition of
LEWIS COLOSIMO

March 15, 2021
9:31 a.m.

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(Appearing Remotely)

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1 THE VIDEOGRAPHER: We're on the
2 record.

3 LEWIS COLOSIMO, of lawful age, called for
4 examination, as provided by the Federal Rules
5 of Civil Procedure, being by me first duly
6 sworn, as hereinafter certified, deposed and
7 said as follows:

8 EXAMINATION OF LEWIS COLOSIMO
9 BY MR. LIVINGSTON:

10 Q. Good morning, Mr. Colosimo. As you
11 know, my name is Scott Livingston and I
12 represent Giant Eagle in this litigation.
13 Before we begin, I just wanted to go over maybe
14 just a couple quick ground rules, if it's okay
15 with you, especially since we're doing this
16 remotely.

17 If for any reason you don't hear a
18 question that I ask you, will you promise to
19 let me know and I can repeat it for you?

20 A. Sure.

21 Q. And if for any reason you don't
22 fully understand a question that I ask you, will
23 you please let me know and I can try to rephrase
24 the question for you? Will you do that?

25 A. Yes.

1 Q. Thank you. Would you introduce
2 yourself to the jury, please?

3 A. Yes. My name is Lewis Colosimo.

4 Q. Where do you reside, sir?

5 A. I reside in Canonsburg,
6 Pennsylvania.

7 Q. Is that more than 100 miles from
8 downtown Cleveland, to your knowledge?

9 A. I believe so.

10 Q. So this might be used as your trial
11 testimony just to kind of forewarn you of that,
12 and that's one reason why we're recording it, if
13 that's all right with you.

14 A. Okay.

15 Q. Could you please briefly describe
16 your educational background?

17 A. I graduated in 1989 from Geneva
18 College with a Bachelor of Arts.

19 Q. What was your major?

20 A. Major was sociology.

21 Q. And what did you do, sir,
22 employment-wise after you graduated?

23 A. I worked as a counselor for
24 juvenile delinquents at Adelphoi Village.

25 Q. When did you graduate -- you said

1 you graduated in 1989; is that correct?

2 A. Yes.

3 Q. And how long were you a counselor at
4 Adelphoi?

5 A. I believe it was approximately one
6 year.

7 Q. And what did you do after that
8 employment-wise?

9 A. I accepted employment with the Drug
10 Enforcement Administration.

11 Q. And so that would have been maybe
12 1990?

13 A. Correct.

14 Q. And are you still with the DEA?

15 A. Yes.

16 Q. Thank you for your long service
17 there, sir.

18 Could you please just run through
19 your positions, if they've changed at all over
20 time while you've been with the DEA?

21 A. Yes.

22 In May of 1990 I was hired as a
23 diversion investigator with the Drug
24 Enforcement Administration, and since that time
25 I have been employed in the Pittsburgh district

1 office as a diversion investigator, and most
2 recently, approximately two weeks ago, I have
3 been the group supervisor, group supervisor for
4 the diversion group in the Pittsburgh district
5 office.

6 Q. And as a group supervisor, do you --
7 I assume you supervise other diversion
8 investigators for the DEA?

9 A. Correct.

10 Q. And would it be fair to say that one
11 of the DEA's missions is to try to prevent the
12 use and sale of illegal drugs?

13 A. I can explain as a diversion
14 investigator one of our duties involves the
15 prevention of the diversion of pharmaceutical
16 controlled substances.

17 Q. Okay. And I mean prescription drugs
18 essentially. Is that what you're talking about
19 with respect --

20 A. Prescription drugs as well as
21 scheduled listed chemicals, such as
22 pseudoephedrine and ephedrine.

23 Q. But does the DEA also try to prevent
24 the use and sale of illegal drugs, like, for
25 example, heroin and cocaine?

1 A. That would be a role of DEA,
2 correct.

3 Q. And then your focus, sir, it sounds
4 like has been as a DEA agent on trying to limit
5 and prevent the diversion of legally prescribed
6 type drugs?

7 A. Yes.

8 Q. Just because I know we're going to
9 be talking a lot about diversion today, can you
10 just define that, what diversion means, for the
11 jury?

12 A. I would define diversion as any
13 unlawful or handling of controlled substances
14 that would be outside of DEA regulations.

15 Q. Okay. Would that essentially be
16 like any kind of criminal act involving, you
17 know, prescription drugs?

18 A. Controlled substance prescription
19 drugs.

20 Q. And what is a controlled substance
21 as opposed to a regular prescription drug?

22 A. Controlled substances are drugs
23 that are classified by DEA as well as the Food
24 and Drug Administration in one of five
25 schedules depending upon their use as

1 legitimate -- for a legitimate medical purpose.
2 These are drugs that have a potential for
3 abuse, potential for addiction and harm.

4 Q. I see. And does the DEA have a
5 schedule of like one through five for these
6 types of drugs?

7 A. Yes.

8 Q. And Schedule 1 are drugs that have
9 really no lawful purpose at all; is that fair to
10 say?

11 A. That's correct, yes.

12 Q. And then Schedule 2 are drugs that
13 have a potentially useful medical purpose but
14 also have a high risk of abuse and are
15 dangerous; is that correct essentially?

16 A. Correct.

17 Q. And then you go down the list, you
18 know, Schedule 3, with lesser severity and
19 lesser risk of abuse; would that be fair to say?

20 A. That is one of the criteria for
21 classifying those drugs.

22 Q. Does diversion include the theft of
23 prescription drugs?

24 A. Yes.

25 Q. And would it include using any kind

1 of deception to obtain a prescription drug?

2 A. That would include that, yes.

3 Q. Forging of a script, for example,
4 that would be a form of diversion?

5 A. Yes.

6 Q. What about, you know, if someone in
7 your family gets a script for, let's say, some
8 sort of opioid as a result of an operation and
9 they don't use all of their drugs, they leave
10 them in their medicine cabinet and their teenage
11 son takes those? Would that still be considered
12 diversion, that sort of use of a prescribed
13 drug?

14 A. Any time the drug is used by
15 someone to whom it's not prescribed would be a
16 form of diversion.

17 Q. So that would include taking
18 grandma's prescription drugs, you know, out of
19 her medicine cabinet?

20 A. That would be an example, yes.

21 Q. Thank you very much.

22 Now, has the DEA enacted a number
23 of regulations to help prevent the diversion of
24 legally prescribed drugs?

25 A. My understanding is that these

1 regulations are in the Code of Federal
2 Regulations.

3 Q. Right. And I was just saying are
4 those DEA regulations essentially -- DEA drafted
5 them, promulgated them, and enforces them?

6 A. I'm not certain how much and what
7 involvement DEA has in the regulations. I
8 can't speak to that.

9 Q. Fair enough. Let me ask a slightly
10 different question.

11 With respect to the regulations
12 that do apply to controlled substances, does
13 the DEA -- one of DEA's jobs is to enforce
14 those regulations?

15 A. I think that would be a -- fair to
16 say, one of our responsibilities.

17 Q. And does the DEA -- well, in order
18 for a doctor to prescribe controlled substances,
19 do they have to have a DEA license to do that?

20 A. Yes. Generally, there would be
21 limited circumstances where a physician that is
22 employed at a hospital may not have their own
23 DEA registration number, but it may, under
24 certain conditions, use the hospital's DEA
25 number for in-hospital practice.

1 Q. But generally a doctor needs to
2 obtain -- in order to prescribe medication as
3 part of their practice, they need to obtain a
4 DEA license to do that?

5 A. Generally, yes.

6 Q. And the same would be true with
7 respect to a pharmacy; that if a pharmacy is
8 going to be dispensing controlled substances,
9 they would need to obtain a DEA license to do
10 that?

11 A. Correct.

12 Q. And I think you mentioned hospitals.
13 Hospitals would likewise have to have a license
14 to prescribe controlled substances?

15 A. Yes, or administer or dispense to a
16 patient.

17 Q. And with respect to distributors who
18 distribute drugs to doctors and pharmacies for
19 ultimate dispensing to the public, do they have
20 to have a DEA license if they're distributing
21 controlled substances?

22 A. They do.

23 Q. Now, in order to or as part of DEA's
24 efforts to enforce these controlled substance
25 regulations, does the DEA require someone who's

1 applying for a license essentially, like a
2 distributor -- let's take a distributor, for
3 example. If a distributor is applying for a
4 license, do you do a -- sort of a
5 pre-authorization inspection of their facilities
6 and everything to make sure that they're in
7 compliance or going to be in compliance with all
8 the applicable regulations?

9 A. Yes, we do an investigation to
10 determine that they're eligible to engage in
11 that activity.

12 Q. What do you call that? Is that a
13 pre-registration inspection or pre-authorization
14 inspection? I'm not sure. What terminology do
15 you use?

16 A. I personally and others that I work
17 with refer to that as a pre-registrant
18 investigation.

19 Q. And are those inspections important
20 in terms of trying to make sure that anybody who
21 has -- any distributor who has a DEA license is
22 going to be able to comply with all of the
23 controlled substance regulations?

24 MS. CARROLL: Objection. Form.

25 The witness may answer.

1 A. Could you repeat the question? I'm
2 sorry.

3 Q. Yes.

4 Well, is that pre-registrant
5 inspection an important tool that the DEA uses
6 to make sure that somebody who is going to be
7 distributing controlled substances with a DEA
8 license is going to be able to comply with the
9 applicable DEA controlled substances
10 regulations?

11 A. That investigation is certainly
12 part of what I'm tasked or a diversion
13 investigator might be tasked to do, certainly.

14 Q. Now, we didn't talk about this
15 earlier when you were mentioning that, you know,
16 you've been with the DEA for many years. Have
17 you always been geographically in western
18 Pennsylvania as a DEA agent?

19 A. A DEA investigator would be the
20 proper -- a diversion investigator. I have
21 worked I indicated exclusively in the
22 Pittsburgh district office, covering western
23 Pennsylvania is our area of responsibility.

24 Q. How many pre-registrant inspections
25 have you either performed or at least been

1 involved with since you've been with the DEA,
2 just roughly, just a general idea?

3 A. That would be a difficult question
4 to answer. These are investigations that I've
5 done throughout the course of my career, but it
6 would be difficult to even give a rough
7 estimate of how many of these I've done.

8 Q. Well, maybe how about in the last
9 year how many have you done, if you can recall?

10 A. You know what, I don't know. Part
11 of this -- part of these investigations involve
12 a gamut of different types of activities. I
13 think any of those probably would have been for
14 a researcher that was using controlled
15 substances for research purposes.

16 Q. Do you have a sense of how many
17 distributors of controlled substances are in
18 your geographical area, the western Pennsylvania
19 area?

20 A. I don't know the exact number. I'm
21 not sure how many that would be. I can't
22 answer that accurately.

23 Q. You're familiar with Giant Eagle?

24 A. Yes.

25 Q. And Giant Eagle is a distributor of

1 controlled substances?

2 A. Yes.

3 Q. And they distribute the controlled
4 substances to their own pharmacies in their
5 grocery stores?

6 MR. MOUGEY: Objection.

7 A. That's my understanding.

8 Q. Meaning that they don't distribute
9 to like other company -- pharmacies owned by
10 other companies, correct?

11 A. To my knowledge, that's correct.
12 I -- I can't say definitively if they don't,
13 but my understanding is that they sell
14 exclusively to Giant Eagle pharmacies.

15 Q. Are you familiar with McKesson as a
16 drug distributor?

17 A. McKesson drug, yes.

18 Q. Okay. And they have a distribution
19 facility in New Castle; is that correct?

20 A. Correct.

21 Q. Have you inspected their facility in
22 New Castle?

23 A. I have.

24 MS. CARROLL: Objection. This is
25 an objection as to the scope of the testimony.

1 Q. Mr. Colosimo, has the DEA trained
2 you in terms of trying to make sure you
3 understand all the controlled substances
4 regulations and what they require? Have you
5 received any training from the DEA with respect
6 to that?

7 A. I have received training, yes.

8 Q. And what has that training involved?

9 A. Well, initially upon hire by DEA, I
10 received training at DEA's academy. It was
11 considered a basic diversion investigator
12 class, and periodically, throughout the course
13 of my career, I received training from DEA.

14 Q. Now, after a registrant obtains a
15 DEA license with respect to controlled
16 substances, does that licensing or registrant
17 have to undergo periodic inspections to make
18 sure that they have remained in compliance with
19 the applicable DEA controlled substance
20 regulations?

21 A. Yes. These registrants, such as a
22 distributor, would be subject to inspections.

23 Q. Are they called cyclic
24 investigations, or inspections? I'm sorry.

25 A. That's -- that's one phrase that

1 has been used.

2 Q. When you do a pre-registrant
3 inspection, what -- can you tell us what that
4 entails, what that involves, what you look at,
5 and how you conduct the inspection?

6 MS. CARROLL: Objection. Form.
7 The witness may answer.

8 A. Pardon me?

9 Q. Yes. I'm just asking you, can you
10 tell the jury what a pre-registrant inspection
11 involves, what do you do as part of that
12 inspection?

13 MS. CARROLL: Objection. Form.
14 The witness may answer.

15 A. Part of that pre-registrant
16 investigation would involve a review of the
17 applicant's security procedures they have in
18 place, any history they may have with the
19 handling of controlled substances or listed
20 chemicals, any proposed recordkeeping that they
21 have in place. It would require an on-site
22 inspection of the facility and a meeting with
23 certain personnel, you know, that would be
24 employed by the applicant that would be able to
25 address questions regarding security,

1 recordkeeping, personnel issues. That would be
2 a general criteria that we consider.

3 Q. And how many diversion investigators
4 typically are involved in a pre-registrant
5 inspection?

6 A. I mean, I could only speak to
7 myself. I don't know how many typically are
8 involved, but from one to several.

9 Q. And does -- is a group supervisor
10 typically involved or does a group supervisor
11 have to approve the inspection?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. A group supervisor may or may not
15 be involved. That would be at their
16 discretion.

17 Q. And if you find that there's
18 anything that is not in compliance with the DEA
19 regulations during a pre-registrant inspection,
20 what do you do about that?

21 A. What I have done would be to bring
22 that to the attention of the group supervisor
23 for discussion.

24 Q. Okay. And then what -- with respect
25 to the registrant or proposed registrant, do you

1 bring that to the registrant's attention, that
2 there's an issue regarding compliance?

3 A. Well, that would be something that
4 would need to be addressed with the applicant.

5 Q. And do you withhold the grant of the
6 license until the proposed registrant has, you
7 know, remedied the non-compliance?

8 A. The decision for that would be the
9 group supervisor's decision whether to approve
10 or to deny the application.

11 Q. Just if you recall -- I know you've
12 been with the DEA for many years, but has that
13 situation ever arisen where a registrant's
14 application was denied that you were involved
15 with?

16 A. That has happened on occasion.

17 Q. Can you identify the -- what you
18 view as sort of the principal sources of
19 diversion that you're on the watch for when
20 you're inspecting registrants?

21 A. Could you be more specific with
22 that question, please?

23 Q. Well, maybe I'll just ask it
24 slightly differently. What, in your view as a
25 DEA inspector, diversion inspector, do you

1 believe are the principal sources of diversion
2 of prescription drugs in your locale?

3 A. I don't know that I could speak to
4 the principal. I know the various forms of
5 diversion that occur, which could happen with
6 any registrant, any type of registrant, but I
7 can't quantify the -- what the principal --
8 that would be speculation.

9 Q. Now, as a DEA diversion inspector,
10 do you also work with other state and federal
11 agencies to try to prevent diversion?

12 A. Yes.

13 Q. Do you work with the FBI sometimes?

14 A. Yes.

15 Q. Do you work with the Pennsylvania
16 Attorney General's Office sometimes?

17 A. Yes.

18 Q. Do you work with the state boards of
19 pharmacy, like the Pennsylvania board?

20 A. We would coordinate investigations
21 occasionally with the various boards within
22 Pennsylvania.

23 Q. And do you work with local law
24 enforcement as well?

25 A. Yes.

1 Q. Do you know a Rick Shaheen?

2 A. Yes.

3 Q. How do you know Mr. Shaheen?

4 A. I know of Mr. Shaheen through his
5 employment with the Pennsylvania Office of
6 Attorney General as well as his position with
7 Giant Eagle.

8 Q. How did you come to know him when he
9 was with the Pennsylvania Attorney General's
10 Office? Did you work on some investigations
11 together?

12 A. Yes. My understanding is that
13 Mr. Shaheen was an agent with the Medicaid
14 fraud unit with the Office of Attorney General,
15 and then later was employed there as a
16 supervisor, supervising other agents within
17 that unit.

18 Q. Okay. And did you actually work on
19 any drug investigation, you know, drug
20 investigations with Mr. Shaheen when he was with
21 the Office of Attorney General?

22 A. Yes.

23 Q. And then you mentioned his position
24 with Giant Eagle. Did he obtain that position
25 around 2013? Does that sound right?

1 MS. CARROLL: Objection. Form.

2 The witness may answer.

3 A. I don't know when he accepted that
4 position. I would be guessing.

5 Q. Well, when do you first recall
6 working with him when he was in his new position
7 with Giant Eagle?

8 A. It's been -- I know he's been
9 employed there for several years. I can't
10 recall the first time that I worked with him.

11 Q. And do you know what his position is
12 with Giant Eagle?

13 A. My understanding, pharmacy
14 investigator.

15 Q. Would you agree that one of
16 Mr. Shaheen's jobs is to help prevent drug
17 diversion?

18 A. That's my understanding of part of
19 what his role is with Giant Eagle.

20 Q. So part of his job is to try to make
21 sure that no drug diversion occurs with respect
22 to Giant Eagle's distribution or pharmacy
23 facilities, right?

24 MS. CARROLL: Objection. Form.

25 The witness may answer.

1 A. I don't know all of his
2 responsibilities of -- what Giant Eagle has
3 tasked him to do.

4 Q. In your dealings with Mr. Shaheen
5 have you found him to be a conscientious and
6 competent with respect to trying to prevent drug
7 diversion?

8 A. I can't -- could you be more
9 specific with that question, please?

10 Q. Well, let me -- have you worked with
11 Mr. Shaheen in trying to catch any bad guys with
12 respect to drug diversion?

13 MS. CARROLL: Objection. Form.

14 Q. You know, any investigations where
15 maybe, you know, Mr. Shaheen has called you up
16 and said, I think we have a bad script here or
17 something like that, you know, has given you
18 information about a potential issue?

19 MS. CARROLL: Objection.

20 A. Yes. I've worked many times with
21 Mr. Shaheen on those types of scenarios,
22 correct.

23 Q. And with respect to your dealings
24 with Mr. Shaheen when you guys are both working
25 together to try to prevent diversion, have you

1 found him to be, you know, conscientious, hard
2 working and devoted toward preventing diversion?

3 MS. CARROLL: Objection. Form.

4 The witness may answer.

5 A. From my perspective, Mr. Shaheen
6 has provided cooperation with -- with DEA, with
7 myself personally on the types of diversion
8 investigations that I have -- that I have
9 worked on. He has offered cooperation.

10 Q. Would it be fair to say that he's
11 always cooperated with you?

12 A. I can't recall of any specific
13 cases where he did not cooperate with me at
14 least outwardly, if that's -- that could be a
15 way to put it. I don't know of any cases where
16 he was not cooperative with me.

17 Q. And would it be fair to say that
18 sometimes he calls you with sort of some
19 information or a tip with respect to an issue
20 and sometimes you call him asking him for some
21 help with respect to an investigation, the
22 relationship goes both ways?

23 MS. CARROLL: Objection to form.

24 The witness may answer.

25 A. I have asked for his cooperation

1 specifically with regard to activity that has
2 occurred at Giant Eagle pharmacies and
3 Mr. Shaheen has provided information, concerns
4 or suspicions regarding diversion to me.

5 Q. Has he sometimes just called you out
6 of the blue with some information about a
7 potential problem or issue relating to drug
8 diversion?

9 A. I don't know that I would say out
10 of the blue, but he has called me with
11 information.

12 Q. And information that you did not
13 previously have?

14 A. I would say that on occasion that's
15 correct.

16 Q. Has Mr. Shaheen always been
17 responsive to any requests you've made of him?

18 A. My understanding is he has been
19 responsive to requests for information for --
20 yes, for information, correct.

21 Q. Now, does the DEA have a diversion
22 investigator's manual?

23 A. Yes.

24 Q. Are you familiar with that manual?

25 A. I'm somewhat familiar with that.

1 Q. And does that manual sort of set
2 forth what is supposed to be done with respect
3 to a pre-registrant inspection and a cyclic
4 inspection?

5 A. My understanding is part of that
6 manual would address some of those issues, yes.

7 Q. Mr. Colosimo, we're going to be now
8 starting to go through some exhibits, and we
9 sent you -- you should have -- it's actually a
10 binder, which we thought might be easier for us,
11 in terms of going through the exhibits, to put
12 them in a binder. If you could pull that binder
13 out, I'd appreciate it. Do you have it handy?

14 A. I have not opened the boxes yet. I
15 would probably need a minute or two to open
16 those.

17 MR. LIVINGSTON: Sure. We can go
18 off the record for a couple minutes. How about
19 a five-minute break? Is that sufficient?

20 THE WITNESS: Would it be both
21 boxes that I received?

22 MR. LIVINGSTON: Well, yeah, so the
23 Plaintiffs sent you a box and Giant Eagle sent
24 you a box. Obviously I'm just going to be
25 asking about my exhibits. But yeah, you could

1 open both boxes, but it's the binder is what
2 we're going to be going through right now.

3 THE WITNESS: Would that be in the
4 banker's box?

5 MR. LIVINGSTON: I think they both
6 would have been in banker's boxes. I'm not
7 sure.

8 THE WITNESS: I'll take a few
9 minutes to open those, if you don't mind.

10 THE VIDEOGRAPHER: We're off the
11 record.

12 (Recess had.)

13 THE VIDEOGRAPHER: We're on the
14 record.

15 BY MR. LIVINGSTON:

16 Q. Mr. Colosimo, periodically do you
17 get directives from your superiors at DEA about
18 particular things that they want you to focus on
19 when you do an investigation?

20 A. Yes, periodically.

21 Q. And just generally, would it be fair
22 to say that there's a number of so-called
23 security regulations that apply to controlled
24 substances that the DEA enforces?

25 A. Yes.

1 Q. And is one of those security
2 regulations the so-called suspicious order
3 monitoring regulation?

4 A. Yes.

5 Q. And just, you know, for ease of
6 reference in the deposition, I may sometimes
7 just refer to that regulation as the SOM
8 regulation. Is that okay with you?

9 A. You're talking about the specific
10 CFR cite for that?

11 Q. Well, yeah. Isn't it 1374?

12 A. 1301.74(b).

13 Q. So is it okay if I refer to that as
14 the SOM regulation?

15 A. Okay.

16 - - - - -

17 (Thereupon, Defendants' Deposition
18 Exhibit 2, Memorandum to Diversion
19 Program Managers from the Diversion
20 and Regulatory Litigation Section,
21 dated March 1, 2007, with Attached
22 Documents, Beginning Bates Stamp
23 CAH_MDL_PRIORPROD_DEA12_00000609,
24 was marked for purposes of
25 identification.)

1 - - - - -

2 Q. If you go to Exhibit 2 in your
3 binder, and the page 9 -- and the pages are at
4 the top.

5 A. Okay.

6 Q. So you see that I pulled this right
7 from the DEA website. This is regulations
8 beginning on 1301.71 called the Security
9 Requirements Generally.

10 Do you see that?

11 A. Yes.

12 Q. Okay. And you're familiar with
13 these security requirements, correct?

14 A. Generally, yes.

15 Q. And one of the -- these security
16 requirements are one of the things that you
17 check when you do a -- both a pre-registrant
18 inspection and a cyclic investigation?

19 MS. CARROLL: Object to form.

20 A. Yes.

21 Q. In 1301.71(a) it says, "All
22 applicants and registrants shall provide
23 effective controls and procedures to guard
24 against theft and diversion of controlled
25 substances."

1 Do you see that?

2 A. Yes.

3 Q. So, again, that's really one of the
4 things that your -- one of the overarching goals
5 is to make sure that a pre-registrant is going
6 to be able to -- is going to have effective
7 controls against diversion, correct?

8 A. That's something that we consider
9 in doing that pre-registrant investigation.

10 Q. And then it goes on to say, "In
11 order to determine whether a registrant has
12 provided effective controls against diversion,
13 the administrator shall use the security
14 requirements set forth in Sections
15 1301.72-1301.76 as the standards for the
16 physical security controls and operating
17 procedures necessary to prevent diversion."

18 So those are the key security
19 regulations that every proposed registrant must
20 be able to comply with, correct?

21 A. Yes.

22 Q. It then goes on to say that there's
23 a number of factors that have to be taken into
24 consideration regarding whether a registrant is
25 meeting or can meet the security requirements,

1 correct?

2 A. Yes.

3 Q. And it also says that strict
4 compliance is not required but rather
5 substantial compliance is what is required with
6 these security regulations, correct?

7 A. That's what it says.

8 Q. And that's what you look for,
9 correct, you look for substantial compliance
10 with these regulations when you do an
11 inspection, correct?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. That is what we consider when we do
15 our inspection.

16 Q. The first factor -- we're not going
17 to go through all these, thankfully, but the
18 first one is the type of activity conducted in
19 processing of bulk chemicals, preparing dosage
20 forms, packaging, labeling, cooperative buying,
21 et cetera. Would this also take into
22 consideration whether you're a self-distributor
23 like Giant Eagle, where you only distribute to
24 your own stores, or whether you distribute to
25 third-party strangers as well?

1 MS. CARROLL: Objection. Form.

2 The witness may answer.

3 A. I don't know if that addresses
4 specifically what you asked. I look at that
5 and it seems to be the type of activity,
6 whether it's a distributor, manufacturer,
7 repackager, relabeler.

8 Q. Well, let me ask you this: Do you
9 take that into consideration when you inspect a
10 distributor, whether they're a self-distributor,
11 like Giant Eagle, or whether they are a
12 distributor, like McKesson, where they
13 distribute to a third party?

14 A. In my experience, that is something
15 that I consider, yes.

16 Q. And would you agree that there is --
17 you know, just as a general matter, there would
18 be less risk of diversion if a distributor is
19 only distributing to its own stores as opposed
20 to a situation where they're distributing to
21 anybody who places an order with them?

22 A. I can't answer that, whether it's
23 less -- less potential for diversion, but that
24 is something that -- that I do personally on an
25 inspection. That is what I do consider.

1 Q. Let me ask you this then: Why do
2 you consider it? What is the relevance of that
3 fact?

4 MS. CARROLL: Objection. Form.
5 The witness may answer.

6 A. And, again, this is based upon my
7 experience, but we look at as far as a
8 distributor goes, they are to know who their
9 customers are and, as best as they can, the
10 customer of their customers, so that would be
11 something that I would consider.

12 Q. Right. And would you agree that if
13 you're only distributing to your own pharmacies,
14 then you obviously know your customers very well
15 because they're your own customers, correct?

16 A. That would depend upon what -- what
17 that applicant has in place. I don't know
18 necessarily how well they know their -- their
19 customer.

20 Q. Well, they would have hired the
21 pharmacist, who is placing the order, correct?

22 A. I'm not sure that I could speak to
23 who actually hired that -- that pharmacist.

24 Q. Well, not who individually -- let's
25 talk about Giant Eagle. Not who individually at

1 Giant Eagle hired, you know, the pharmacist at
2 store X, but that Giant Eagle hired its own
3 pharmacist.

4 MS. CARROLL: Objection. Form.
5 The witness may answer.

6 A. In this case, my understanding is
7 that these pharmacies that Giant Eagle would
8 have distributed to are owned or operated by
9 Giant Eagle, so -- and, again, I don't know who
10 actually hired them, but they're -- they're
11 Giant Eagle pharmacies, pharmacists.

12 Q. So another thing that you look at --
13 number 2, it says, "The type and form of
14 controlled substance handled," so would that
15 include whether they're handling Schedule 2s or
16 Schedule 3s or some other schedule?

17 A. That particular cite, yeah, that
18 could be the schedule.

19 Q. And wouldn't -- would you have
20 even -- in terms of like Schedule 2, obviously,
21 would you have more concern about security for
22 Schedule 2 drugs than you would about Schedule 3
23 drugs?

24 A. Well, in my experience, and my
25 understanding is that the handling of Schedule

1 2 drugs requires a greater amount of actual
2 physical electronic security at that facility.

3 Q. Because those drugs are more
4 dangerous, correct, there's more of a concern
5 about those drugs, you know, being diverted?

6 MS. CARROLL: Objection. Form.

7 The witness may answer.

8 A. And, again, going back to how DEA
9 has classified a schedule 2 as a drug that has
10 more of the potential for abuse, but any -- all
11 controlled substances by being controlled there
12 is a -- there is a concern that those drugs
13 could be diverted, so we would -- we want to
14 see adequate security, physical security, for
15 any controlled substance.

16 Q. Just as a general matter, would you
17 agree that the security requirements are less
18 stringent for Schedule 3 through 5 drugs than
19 they are for Schedule 2 drugs?

20 A. The physical security for that
21 would be more strict for Schedule 2 than it
22 would be for the Schedules 3s, 4s and 5s.

23 - - - - -

24 (Thereupon, Defendants' Deposition
25 Exhibit 6, 2013 Diversion Manual

1 Excerpt, Beginning Bates Stamp
2 CAH_MDL2804_02145395, was marked
3 for purposes of identification.)

4 - - - - -

5 Q. Would you turn to Exhibit 6, please?
6 Do you see that this is a -- it's not the whole
7 manual because I didn't want to kill trees, but
8 it's at least a portion of the diversion manual
9 for -- this one is dated 2013.

10 Do you see that?

11 A. Yes.

12 Q. Does a new manual come out every
13 year or is it only updated every once in a
14 while? Is this the most current version? Can
15 you help us out there?

16 MS. CARROLL: Objection. Form.

17 The witness may answer.

18 A. I don't know.

19 Q. Do you know which version you are
20 working with today? If we went to your office
21 and we pulled out a copy of the manual, which
22 one would we see?

23 MS. CARROLL: Objection. Form.

24 The witness may answer.

25 A. I don't know -- I don't know what

1 year the current one I'm working with would be,
2 so I can't answer that.

3 Q. Would you go to page 13 at the top
4 of this manual? You see the heading here is
5 Cyclic Investigations of Nonpractitioner CSA
6 Registrants? Do you see that?

7 A. Yes.

8 Q. A nonpractitioner would include a
9 distributor of controlled substances?

10 A. That's my understanding.

11 Q. And then if you skip down, there's a
12 paragraph beginning, "Full in-depth
13 investigations shall be conducted at least once
14 every three years for nonpractitioners."

15 Is that your understanding, that
16 every -- at least every three years you try to
17 perform a cyclic investigation on all
18 distributors in your area?

19 MS. CARROLL: Objection. Form.

20 Witness may answer.

21 A. I don't know what the current
22 policy is. In my experience, this -- this rate
23 of inspection has changed over the course of
24 time, so I don't know what the current --
25 current schedule is, whether it's once every

1 three years or longer.

2 Q. Well, generally, how often did you
3 do cyclic investigations of distributors since
4 you've been with the DEA? How often do you
5 generally try to do that; once every five years,
6 once every two years, you know, once every
7 three, whatever it might be?

8 A. I can't recall specifically. I
9 know it's -- from my memory, it would be once
10 every -- once every few years. So I can't
11 recall specifically that. It may depend upon,
12 you know, certain factors. So I don't know
13 what -- I don't know exactly.

14 Q. It says, "Emphasis shall be given to
15 inventory/recordkeeping, follow-up verification
16 of customers and orders, security, intelligence
17 collection and case support."

18 Does security include the SOM
19 system that the distributor has? Is that
20 something that you look at when you do a cyclic
21 investigation?

22 A. I believe that that SOM that you
23 referred to is in the security part of the
24 investigation.

25 Q. So that is something that you

1 yourself, when you do a cyclic inspection, look
2 at?

3 A. Yes.

4 Q. Could you go to page 130? Do you
5 see this is the section of the manual that
6 applies to pre-registration investigations?

7 A. I see that.

8 Q. And in the middle of that first
9 introductory paragraph it says, "The purpose of
10 the pre-registration investigation is to
11 determine the fitness and suitability of
12 registration investigation" -- I'm sorry, "of
13 the applicant to engage in the activities for
14 which registration is requested."

15 Would you agree with that statement
16 of purpose? Is that your understanding as well
17 for pre-registration inspections?

18 MS. CARROLL: Objection. Form.

19 The witness may answer.

20 A. That's what it states in the
21 manual.

22 Q. And that's your understanding as
23 well?

24 MS. CARROLL: Objection. Form.

25 Witness may answer.

1 A. That's my understanding, yes.

2 Q. At the bottom of that page under the
3 heading Pre-Registration Investigations, it
4 says, "An on-site investigation is required for
5 each applicant."

6 Do you see that statement?

7 A. Yes.

8 Q. Is that true that, in fact, whenever
9 you do a pre-registration inspection, it always
10 includes -- at least a portion of it is on-site?

11 A. For a distributor pre-registration
12 investigation, it would be in my experience.

13 Q. And do you try to be -- when you go
14 on-site and you do your inspection, do you try
15 to be as thorough as possible when you do that
16 inspection?

17 A. Personally, I make sure that I'm
18 thorough, yes.

19 Q. If you go to the next page, page
20 131, paragraph number 1, it indicates, "All
21 pre-registration investigative reports will
22 include information concerning the specific
23 controlled substances to be handled," and, you
24 know, it goes on to list a number of things.
25 And then it says, "The investigative report

1 should include a description of the security
2 maintained by the applicant, a description of
3 the recordkeeping and any other special
4 requirements planned by the applicant, and a
5 summary of an interview conducted with the
6 researcher's supervisor, verifying the
7 researcher's approval to conduct research."
8 Again, the security -- the reference to a
9 description of the security to be maintained,
10 does that include the suspicious order
11 monitoring system that the registrant plans to
12 use?

13 A. This particular site here, it looks
14 like it's just addressing researchers to me.

15 Q. As opposed to a distributor?

16 A. Yes.

17 Q. Well, let me just ask you this:
18 When you do a pre-registration inspection, you
19 do always look at the distributor's proposed SOM
20 system to make sure that it complies or will
21 comply with the SOM regulation?

22 A. We would look at the -- I would
23 want to know if they have a -- if they have a
24 system that they're going to be using to detect
25 suspicious orders.

1 Q. Do you conduct any kind of inventory
2 check of the proposed registrant's drugs?

3 A. Well, because it's a pre-registrant
4 investigation, they should not have any
5 controlled substances on hand, so there would
6 not be an inventory check.

7 Q. Do you explain to the applicant what
8 the inventory requirements are under the
9 Controlled Substances Act?

10 A. That is what I do on a
11 pre-registrant investigation, yes.

12 Q. Can we go back to Exhibit 2 for a
13 minute, page 16? Sorry for moving around so
14 much. Do you see that this is the specific SOM
15 regulation, Section 1301.74?

16 A. Yes.

17 Q. It says, number one, "Before
18 distributing a controlled substance to any
19 person who the registrant does not know to be
20 registered to possess the controlled substance,
21 the registrant shall make a good faith inquiry
22 either with the administration or with the
23 appropriate state controlled substances
24 registration agency, if any, to determine that
25 the person is registered to possess the

1 controlled substance."

2 So getting back to the Giant Eagle
3 situation, Giant Eagle would already have this
4 information readily available as to whether or
5 not its pharmacists and pharmacies have a
6 current DEA controlled substance license,
7 correct?

8 A. Well, as part of my pre-registrant
9 investigation, I would inform them that it's
10 their obligation to determine if their customer
11 has a valid DEA registration that's not expired
12 and it's a current, valid registration. So
13 they're -- I tell them that it's their
14 obligation to determine that.

15 Q. Right. But that information would
16 be just something that Giant Eagle would already
17 have in its possession; it wouldn't have to make
18 a phone call to somebody because it already has
19 that in its own records, correct?

20 MS. CARROLL: Objection. Form.
21 Asked and answered.

22 The witness may answer.

23 A. I don't know exactly what
24 information they would have in their system to
25 determine that.

1 Q. Well, you would hope that they would
2 have -- as part of any good recordkeeping, a
3 corporation should keep track of all of its
4 active DEA licenses, correct?

5 A. That's what their responsibility
6 is, is to not sell to any customer that does
7 not have a valid DEA registration.

8 Q. So subparagraph B in the SOM
9 regulation says, "The registrant shall design
10 and operate a system to disclose to the
11 registrant suspicious orders of controlled
12 substances. The registrant shall inform the
13 field division office of the administration in
14 his area of suspicious orders when discovered by
15 the registrant. Suspicious orders include
16 orders of unusual size, orders deviating
17 substantially from a normal pattern, and orders
18 of unusual frequency."

19 That's the SOM regulation, correct,
20 or at least a key part of the SOM regulation,
21 correct?

22 A. Yes.

23 MS. CARROLL: Objection to form.

24 Q. And would it be fair to say that the
25 DEA does not further define what they mean by

1 unusual size or orders deviating substantially
2 from a normal pattern and orders of unusual
3 frequency?

4 A. My understanding is that that's the
5 obligation of the -- of the registrant to
6 define those factors.

7 Q. Right. In other words, you don't --
8 the DEA doesn't endeavor to try to define those
9 terms?

10 A. I don't know if DEA has defined
11 those terms. My understanding, again, as I
12 mentioned, is that the obligation is on that
13 registrant to determine -- determine those.

14 Q. Now, in paragraph C it says, "The
15 registrant must notify the field division office
16 of the administration in his or her area in
17 writing of any theft or significant loss of any
18 controlled substances within one business day of
19 discovery of the theft or loss."

20 When it says "field division office
21 of the administration," would that be like
22 somebody like yourself? Would you receive
23 these sorts of reports if there's been a theft?

24 MS. CARROLL: Objection. Form.

25 The witness may answer.

1 A. Well, my understanding, and this is
2 what I've, in my experience, tried to
3 communicate to the registrants, is that they're
4 obligated to notify the Pittsburgh district
5 office. Now, the field division office, our
6 field division office is in Philadelphia,
7 Pittsburgh is a division of that, but
8 personally I've instructed registrants to
9 notify the Pittsburgh district office, so we
10 are aware of that, there's no time lag from the
11 time that the theft occurs to when we're
12 notified.

13 Q. And is there some sort of like
14 standard for, you know, how much theft, you
15 know, raises alarm bells versus a theft that's
16 considered pretty minor and doesn't raise any
17 alarm bells?

18 A. My understanding is -- of that
19 particular regulation is it's any theft.
20 Whether you think it's minor or insignificant,
21 it's any theft, but it's up to the registrant
22 to determine what they think is a significant
23 loss, but it's any -- any theft.

24 Q. And would it be fair to say, though,
25 that almost any registrant eventually may have

1 some minor theft that they end up reporting?

2 MS. CARROLL: Objection. Form.

3 Q. Or unaccounted for, you know, loss
4 of inventory?

5 A. I'm sorry. I --

6 MS. CARROLL: Same objection.

7 Q. Would it be fair to say that almost
8 every registrant eventually over time ends up
9 reporting occasionally unaccounted for loss of
10 inventory?

11 MS. CARROLL: Objection to form.

12 The witness may answer.

13 A. I don't know the answer to that. I
14 can't quantify whether it's every registrant or
15 a certain percentage that you're expected to
16 have thefts or losses.

17 Q. Do you inspect Giant Eagle's
18 pharmacies or do you only inspect Giant Eagle's
19 distribution facilities?

20 A. I have personally -- I'm not sure
21 if the proper term would be inspect, but I've
22 gotten the consent through a notice of
23 inspection to review records at Giant Eagle
24 pharmacies. I have done that throughout the
25 course of my career.

1 Q. I'm sorry. Can you repeat? I
2 didn't follow that. You said you've gotten
3 requests to review records at Giant Eagle
4 pharmacies?

5 A. If I could give an example --

6 Q. Yes, please.

7 A. -- that would clarify. If -- for
8 example, if we have information that a certain
9 pharmacy has filled prescriptions that we want
10 to look at the actual prescription, I would go
11 to the pharmacy, receive written consent of
12 that pharmacist to review records. Now, I
13 don't necessarily characterize that as an
14 inspection of everything that's going on there,
15 but it would be an inspection of what I'm
16 focusing on for that particular visit. So
17 it's -- it's a DEA notice of inspection that
18 I'm reviewing with that pharmacist in charge,
19 but that -- it wouldn't necessarily be a
20 full-scale inspection. It could just be a
21 review of a limited part of what -- what I need
22 to know.

23 Q. Right. So if you're investigating
24 somebody maybe who's like getting forged scripts
25 filled, you might, you know, want to inspect

1 those scripts and that's when you would make
2 this request of a pharmacy?

3 A. Yes.

4 Q. Have you ever been in a situation
5 where a -- as part of an investigation, cyclic
6 investigation, you found that the registrant was
7 not complying with the security regulations and
8 you ended up pursuing some sort of enforcement
9 action or anything along those lines?

10 MS. CARROLL: Objection. Form.

11 The witness may answer.

12 A. What specific type of registrant
13 are you asking about?

14 Q. Let's talk about -- we're focusing
15 on distributors right now.

16 A. I can't recall specifically. I
17 would be speculating about what type of
18 enforcement action. And I wouldn't
19 characterize it as an enforcement action. It
20 could be an administrative action. But I can't
21 recall specifically that that happened in a
22 scheduled investigation or cyclic investigation
23 that I was part of with a distributor. I may
24 have, but I can't recall specifically.

25 Q. Why don't we go to Exhibit 6, page

1 137. Do you see under paragraph D it says,
2 "Denial of DEA Form 225 Application"? What is a
3 DEA Form 225 Application?

4 A. That's an application that would be
5 used by a number of different types of
6 registrants, including -- or applicants,
7 including a -- someone seeking registration as
8 a distributor.

9 Q. Okay. And it says, "The denial of
10 any application for registration must be
11 pursuant to an order to show cause proceeding."

12 Have you ever been involved in that
13 where there's been a denial of an application,
14 of a Form 225 application?

15 A. I don't know. I don't know. I may
16 have been party to that investigation, but I
17 don't recall being the lead investigator on
18 such an application.

19 Q. And under that same paragraph, if
20 you go to the next page, page 138, under number
21 3, it says, "Revocation, denial, or surrender of
22 registration where there was suspected reason to
23 cause a registration to be revoked or
24 surrendered or to cause denial of registration,
25 an investigation is required to document the

1 circumstances."

2 Have you ever been involved in any
3 situation like that, where there's a
4 revocation, denial or surrender of registration
5 and, as a result, you've done an investigation,
6 a further investigation?

7 MS. CARROLL: Objection. Form.

8 Witness may answer.

9 A. Again, this would be what --
10 similar to what I answered just a moment ago,
11 was that I may have been party to such an
12 investigation, but I don't recall being the
13 primary investigator on -- specifically with
14 regard to a distributor, revocation, denial or
15 surrender for controlled substances.

16 Q. Number 4, it says, "Failure to
17 maintain adequate controls against theft and
18 diversion." And is it your understanding that
19 can be one of the reasons for the DEA seeking to
20 revoke, deny or cause the surrender of a
21 registrant's license?

22 A. My understanding is that is
23 something that we would consider, yes.

24 Q. If you do uncover any shortcomings
25 in a security system used by a distributor when

1 you're inspecting them, do you have a discussion
2 with management about that? Is that something
3 that you would discuss with them?

4 MS. CARROLL: Objection. Form.
5 Witness may answer.

6 A. Whether it's a pre-registrant or a
7 scheduled investigation, that is something that
8 we would -- that I would want to discuss with
9 management.

10 Q. Would you go to page 162 of Exhibit
11 6? There's a heading there, Discussion with
12 Management. "At the discretion of the group
13 supervisor, the investigators should discuss
14 their findings with him/her prior to discussing
15 the alleged violations with the firm's
16 management. Significant recordkeeping
17 discrepancies should be supported with
18 documentation."

19 And then number 2, it says, "The
20 firm should be informed of what courses of
21 action against it are possible but not the
22 specific action the investigators intend to
23 recommend."

24 Do you see that?

25 A. Yes.

1 Q. So that's the kind of management
2 discussion that you were referring to?

3 A. Discussion with DEA management,
4 then continuing with management of the -- of
5 the applicant or the registrant. And, again, I
6 don't know -- you're referring to this manual.
7 I don't know -- I'm not sure what version or if
8 this is in the current DEA manual. I don't
9 know. I'm not certain what version this is
10 that's on the screen.

11 Q. All right. So number 3 says, "The
12 investigators should suggest changes that could
13 be made in the firm's operation for the purpose
14 of achieving compliance."

15 Is that something that you've done,
16 you know, over the years, from time to time
17 you've made recommendations to registrants?

18 MS. CARROLL: Objection. Form.

19 The witness may answer.

20 A. I have made those suggestions, yes.

21 Q. And number 6, it says, "The
22 discussion with management should either
23 reinforce the investigators' findings by the
24 firm's acceptance of the cited violations and
25 willingness to correct them or challenge the

1 investigators' findings by non-acceptance of the
2 violations pointed out."

3 Is that your understanding as well,
4 that you have -- when you have that discussion,
5 either the management will accept those
6 findings or they may sometimes challenge those
7 findings and you have to deal with that
8 situation if they challenge them?

9 MS. CARROLL: Objection. Form.

10 The witness may answer.

11 A. That has happened from time to time
12 on investigations.

13 Q. Then it says -- if they're going to
14 challenge it, then it says, "The investigators
15 should attempt to understand the firm's opinions
16 and reasons for them. If the firm's position is
17 reasonable, the investigators should verify the
18 information and take appropriate action.
19 Investigators must control the direction and
20 tone of this discussion. At no time should it
21 be allowed to degenerate into an uncontrollable
22 argument."

23 Is that how you've tried to -- you
24 know, to do your -- or have your discussions,
25 which is you try to hear out the registrant and

1 then -- but, you know, keep it civil and
2 professional at all times?

3 MS. CARROLL: Objection. Form.
4 Witness may answer.

5 A. I attempt to be professional in any
6 part of my investigations with registrants or
7 even non-registrants.

8 Q. I'd like to now just focus on Giant
9 Eagle inspections. Can you just summarize what
10 inspections you've been involved with with
11 respect to Giant Eagle?

12 A. My recall is I was involved with at
13 least one inspection of HBC in Washington with
14 regard to their handling of scheduled listed
15 chemicals. That would be their sale of
16 over-the-counter products containing
17 pseudoephedrine or ephedrine.

18 I was involved with a
19 pre-registrant investigation of HBC several
20 years ago when they requested authorization to
21 handle Schedules 3, 4 and 5 controlled
22 substances at their facility in Washington,
23 Pennsylvania.

24 I was involved with a
25 pre-registrant investigation of Giant Eagle Rx

1 Distribution Center in Freedom, Pennsylvania --
2 this was four or five years ago -- when they
3 sought to handle or distribute Schedules 2
4 through 5 controlled substances.

5 Q. Any other investigations or
6 inspections of Giant Eagle?

7 A. I think I mentioned earlier that my
8 inspections -- my visits, discussions with
9 pharmacists at the various Giant Eagle
10 pharmacies, if that's --

11 Q. I was just referring to the
12 distribution facilities.

13 A. Yeah, that would be on-site
14 inspection, and there may have been -- I don't
15 know that it entailed an on-site inspection,
16 but there was discussion with Giant Eagle
17 regarding certain reporting of the sale of
18 Schedule 2 controlled substances through ARCOS,
19 but I don't -- I don't recall if that entailed
20 an on-site visit.

21 Q. When was that?

22 A. I don't recall specifically when
23 that was.

24 Q. So I think you mentioned you did at
25 least one inspection with respect to listed one

1 chemicals when Giant Eagle -- with respect --
2 when Giant Eagle was -- well, why don't you
3 explain to the jury what a Schedule 1 chemical
4 is and why Giant Eagle needed to be inspected
5 for those chemicals.

6 A. My understanding is Giant Eagle
7 operated HBC, which was a facility, a warehouse
8 in Washington, Pennsylvania. They were selling
9 what could be described as scheduled, listed
10 chemicals. That would be the drugs
11 pseudoephedrine and ephedrine in
12 over-the-counter form, for example, Sudafed.
13 In order to sell that product to a customer,
14 HBC had to have a registration with DEA to
15 distribute that -- those particular products to
16 their stores.

17 Q. And was it just one inspection that
18 you did or was it more than one with respect to
19 Schedule 1 chemicals?

20 A. You're describing Schedule 1
21 chemicals, that -- it may -- it may be a List 1
22 chemical, but it's an over-the-counter product
23 containing those drugs. I don't know -- I know
24 I was involved with one. There may have been
25 more, but I can't recall specifically more than

1 one.

2 Q. And do the same regulations that
3 we've been talking about, the security
4 regulations, including the SOM regulation, apply
5 to somebody who has a -- a distributor who has a
6 DEA license for List 1 chemicals?

7 A. I don't think -- my understanding
8 is that the security is different for someone
9 who's handling Schedules 2 through 5 controlled
10 substances as opposed to List 1 chemicals.

11 Q. Was the inspection that you did of
12 Giant Eagle's HBC facility with respect --
13 relating to listed -- list 1 chemicals, did you
14 find any violations or did you find that they
15 were in compliance?

16 MS. CARROLL: Objection. Form.
17 Witness may answer.

18 A. My recollection is that there were
19 no administrative sanctions, which would
20 include something like a -- along the lines of
21 a letter of admonition. I don't recall that
22 that ever happened on my inspection.

23 Q. Does it mean that Giant Eagle was in
24 compliance with all of the regulations that
25 apply to somebody who distributes list 1

1 chemicals?

2 A. For that specific investigation, I
3 know there was no formal administrative
4 sanction, but I don't recall specifically if
5 there were any -- any concerns or issues with
6 their compliance that may have been addressed
7 short of a formal administrative section.

8 - - - - -

9 (Thereupon, Defendants' Deposition
10 Exhibit 19, Report of Investigation
11 dated October 26, 2009, Beginning
12 Bates Stamp DEA-T1BCC-00001833, was
13 marked for purposes of
14 identification.)

15 - - - - -

16 Q. Can you please turn to Exhibit 19,
17 page 1? You see this is a report of
18 investigation and it says it's by yourself? Do
19 you recognize this exhibit?

20 A. I do, yes.

21 Q. Is this a report that you prepared?

22 A. It appears to be, yes.

23 Q. At the bottom it says signature of
24 agent and your name is indicated there dated
25 11-4-2009. Is that your signature?

1 A. Yeah, it looks like it was
2 electronically signed.

3 Q. And then it says approved by Kurt G.
4 Dittmer, group supervisor. Was Mr. Dittmer your
5 group supervisor at the time?

6 A. Yes.

7 Q. And he did, in fact, approve this
8 report?

9 A. Yes.

10 Q. And this report is with respect to
11 Giant Eagle's request for a DEA license to
12 distribute Schedule 3 through 5 controlled
13 substances, correct?

14 A. Yes.

15 Q. Your understanding was HBC was Giant
16 Eagle's warehouse where they were going to --
17 out of which they were going to distribute drugs
18 to their own pharmacies, and it was located in
19 Washington, Pennsylvania?

20 A. Yes.

21 Q. And then at the very bottom of the
22 first page, it says, "Carlson informed DI
23 Colosimo that HBC Service Company will
24 distribute Schedule 3-5 controlled substances to
25 over 200 Giant Eagle pharmacies in Pennsylvania,

1 West Virginia, Maryland and Ohio."

2 That's always been your
3 understanding ever since you've dealt with
4 Giant Eagle, that they've always distributed
5 controlled substances only to their own
6 pharmacies, correct?

7 A. Whether they did or not, I can't
8 say, but that -- you're correct, that's my
9 understanding, that they were only selling to
10 Giant Eagle pharmacies.

11 Q. Yeah, I wasn't suggesting that you
12 were, you know, literally, you know, at the
13 facility 24/7 making sure that every order went
14 to a Giant Eagle pharmacy, but just that your
15 understanding from Giant Eagle officials who are
16 certainly under obligation to be truthful with
17 you at all times was that they only distributed
18 controlled substances to their own pharmacies?

19 A. Yes.

20 Q. And why did you note that
21 information here on this report?

22 A. Personally, that would be part of
23 my pre-registrant investigation, to identify
24 the potential customers of the applicant.

25 Q. At the very bottom of the page it

1 says, "He," referring to Carlson, "indicated
2 these pharmacies will continue to receive
3 Schedule 2 controlled substances from their
4 current supplier, McKesson Corporation."

5 Was that your understanding when
6 you did this investigation, that all controlled
7 2 substances dispensed by Giant Eagle
8 pharmacies were going to be supplied by the
9 McKesson company?

10 A. That's what I wrote in the report
11 and that's my recollection, yes.

12 Q. And to the extent that McKesson --
13 and McKesson would have been supplying Giant
14 Eagle's facilities out of its New Castle
15 distribution center, correct?

16 A. Yeah. And, again, my understanding
17 is that McKesson has a number of warehouses
18 throughout the country, but New Castle -- my
19 understanding is that they would have been one
20 of those warehouses.

21 Q. And you would have also inspected or
22 somebody from your office would have inspected
23 McKesson's New Castle facility?

24 MS. CARROLL: Objection. Scope.

25 The witness is directed not to

1 answer.

2 MR. LIVINGSTON: Well, I think that
3 this is related to the -- to Giant Eagle's --
4 whether Giant Eagle was complying with the
5 security regulations because they were being
6 supplied by McKesson, and it's noted in his
7 report.

8 MS. CARROLL: I'm looking at item 3
9 on the Touhy letter. It specifies the
10 inspections of Giant Eagle distribution
11 facilities.

12 MR. LIVINGSTON: Right, and that's
13 what we're looking at, and there's a reference
14 to McKesson, so I think I can try to explore
15 why the word "McKesson" appears in this report.

16 MS. CARROLL: I think you've
17 explained that, but your question goes to
18 additional inspections not done by Mr. Colosimo
19 and not summarized in this report of a
20 non-Giant Eagle facility.

21 Q. Would you skip down to the middle of
22 the page? It says, "Subject Firm's Background."
23 And in the middle paragraph it says, "HBC
24 Service Company, hereinafter referred to as HBC,
25 was approved as a distributor of List 1

1 chemicals on August 27, 1997, and was assigned
2 DEA registration number" -- I won't read the
3 number. "The subject firm was the subject of
4 in-depth cyclic investigations 2002, 2004 and
5 2008."

6 Which one of those investigations
7 did you perform?

8 A. I don't know.

9 Q. And then it says, "No violations
10 were uncovered during these investigations --
11 "during these in-depth investigations." Do you
12 stand by that statement? Is that a true
13 statement?

14 A. My understanding, no formal
15 violations where there would have been any
16 administrative action was taken.

17 Q. Well, it doesn't say no -- it just
18 says, "No violations were uncovered." Are you
19 suggesting that there were violations that were
20 found but nobody did anything about them?

21 A. I don't want to -- I'm not
22 suggesting that. I'm just saying that there
23 may have been issues that were discussed but
24 there's no -- they were not cited for violating
25 any -- any regulations.

1 Q. I mean, when you wrote this report,
2 it was your understanding that the prior
3 investigations of Giant Eagle had revealed that
4 they were in compliance with all applicable DEA
5 security regulations?

6 MS. CARROLL: Objection.

7 The witness may answer.

8 A. As far as those investigations
9 would go, that there were no violations that
10 were uncovered during those investigations.

11 Q. Okay. Now, under Recordkeeping it
12 says that you provided Mr. Carlson with a
13 current copy of 21 CFR 1300 to end and then you
14 said -- it goes on to say that you also provided
15 Carlson and Zelaski with a one-page document,
16 see attachment, which listed CFR references for
17 the following topics particularly relevant to
18 drug distributors, and one of the things that's
19 listed there is reporting suspicious orders.
20 That's the SOM regulation, correct?

21 A. Yes.

22 Q. And so one of the things that you
23 were looking closely at during this
24 investigation was whether Giant Eagle was going
25 to be able to comply with the SOM regulation

1 when they opened for business?

2 MS. CARROLL: Objection. Form.

3 Witness may answer.

4 A. Ask the question again. I'm sorry.

5 Q. Yes. So one of the things that you
6 were looking closely at was whether Giant Eagle
7 was going to be able to comply with the SOM
8 regulation when it opened for business?

9 A. Well, since they had not handled
10 controlled substances at that point, I don't
11 know that they were able to comply, but I was
12 notifying them of the specific CFR requirement
13 to design and operate the suspicious order
14 system.

15 Q. If you go to the next page, at the
16 very top, page 3, it says, "DI Colosimo reviewed
17 each of these items with Carlson, Zelaski,
18 Fleming, and Beiter" from Giant Eagle. So you,
19 in fact, had a discussion with them about, among
20 other things, the SOM regulation, correct?

21 A. Yes.

22 Q. And then if you go down to the
23 middle of the page, there's a paragraph that
24 says, "According to Carlson, HBC will store all
25 original purchase and sales information at their

1 corporate headquarters."

2 Was that your understanding, that
3 there would be some oversight of the HBC
4 operation from the corporate headquarters for
5 Giant Eagle in Pittsburgh?

6 A. That particular statement there I
7 think was specifically regarding central
8 recordkeeping, that any -- you know, the hard
9 copy files, which could be voluminous, were
10 going to be stored at their corporate
11 headquarters.

12 Q. Right. But these records would give
13 officials at the corporate office information
14 regarding what HBC was buying and what HBC was
15 selling and distributing to Giant Eagle stores,
16 correct?

17 A. Those records would be at those
18 headquarters, corporate headquarters, but I
19 don't recall what specific oversight corporate
20 headquarters had.

21 Q. Was it your understanding that HBC
22 was only -- with respect to opioids, opioid-type
23 drugs, that HBC was only going to be
24 distributing to its own -- to Giant Eagle's own
25 pharmacies hydrocodone combination products?

1 A. Well, at the time that that was --
2 the application was submitted, hydrocodone
3 would have been, in my understanding, in
4 Schedule 3, so any -- any controlled substances
5 in Schedules 3, 4 and 5, they had the potential
6 or the authorization to distribute, including
7 hydrocodone.

8 Q. Which is an opioid, correct?

9 A. Yes.

10 Q. Could you go to page 4? The third
11 paragraph from the bottom, towards the end of
12 that paragraph, says, "According to Zelaski, the
13 firm has not had any break-ins since they were
14 registered by DEA in 1997 to handle List 1
15 chemicals."

16 Why did you decide to include that
17 information? Was that because it sort of gave
18 you some comfort that they did not have a lot
19 of theft issues?

20 A. Personally, that's something that I
21 would consider, looking at the adequacy of
22 their physical security, their history of, in
23 this case, handling List 1 chemicals. I would
24 want to know -- that's part of the criteria
25 that's used to review physical security.

1 Q. At the very bottom, the last
2 sentence on this page, it says -- it's referring
3 to Zelaski. "He stated that the firm has a
4 'zero tolerance' policy with respect to employee
5 pilferage, which means that an employee caught
6 stealing merchandise is immediately terminated
7 from employment."

8 Did you consider this policy to be
9 a good policy in terms of helping prevent
10 and/or minimize diversion?

11 A. And, again, that's something that
12 personally, in my experience, that I consider,
13 you know, with employees that have access to
14 controlled substances, that if they're dealing
15 with those employees that are caught, that
16 that's -- that's something that would be --
17 that I would consider with -- as part of their
18 physical security, personnel security.

19 Q. Right. But you would rather see
20 this kind of policy, which is zero tolerance, as
21 opposed to a policy that said that, you know,
22 with respect to pilferage, we give, you know, an
23 employee three strikes before they're out,
24 right? I mean, isn't this a more serious
25 repercussion for any employee who might be

1 tempted to steal controlled substances from the
2 HBC warehouse?

3 MS. CARROLL: Objection. Form.
4 The witness may answer.

5 A. That would be a more serious
6 policy.

7 Q. If you go to the next page, 5, at
8 the top, at the very end of that paragraph it
9 says, "All elements of this cage meet the
10 requirements specified in 21 CFR 1301.72(b)(4)."
11 Is that correct that, in fact, Giant Eagle's
12 proposed steel cage for the storing of Schedule
13 3 through 5 drugs met all of the applicable
14 controlled substance regulations?

15 A. That was my understanding.

16 Q. And then if you skip down to the
17 second paragraph on the bottom, "All HBC team
18 members with access to the cage or those
19 involved in handling the controlled substances
20 will undergo the required background checks
21 associated to the following DEA regulations in
22 21 CFR part 1300."

23 So is that a requirement that if
24 anyone is going to have access to controlled
25 substances, that they have to have a background

1 check that meets the DEA requirements?

2 A. I can't recall specifically those
3 CFR cites there, but my understanding is that
4 there are certain requirements with respect to
5 felony arrests, convictions, which I think are
6 addressed in those, at least one of those --
7 those CFR citations.

8 Q. Would you go to page 7 of Exhibit
9 19? And then there's a heading for Selection.
10 "All selection will be performed using Vocollect
11 directed activity. The Vocollect system will
12 direct users via headset to the location and
13 quantity of each item to select."

14 Do you recall learning about Giant
15 Eagle's Vocollect system when you went out to
16 inspect the HBC facility in 2009?

17 A. I recall some discussion of that.
18 I can't recall the specifics on that Vocollect
19 system.

20 Q. Doesn't the Vocollect system
21 essentially give Giant Eagle a constant
22 real-time understanding of its inventory, so as
23 soon as an item is selected, that's
24 automatically electronically picked up and so
25 Giant Eagle knows at all times what it has in

1 inventory with respect to all products,
2 including its controlled substances?

3 MS. CARROLL: Objection. Form.
4 The witness may answer.

5 A. That was a long question. My
6 understanding is that it had some interface
7 with their computer, but I can't recall
8 specifically the -- how that all worked, but
9 that there was a connection with their --
10 whatever computer the Giant Eagle would have to
11 record their activity.

12 Q. So it says that the -- "As the
13 selector is picking, they will scan the NDC bar
14 code of the item to ensure that the exact item
15 is being selected. This will be repeated for
16 all items until all total units are selected.
17 (These tasks are completed one customer at a
18 time.)" So that for each pharmacy, using the --
19 when the picker is using the Vocollect system,
20 Giant Eagle is getting a constant readout of
21 what has been selected and what has been put in
22 the tote for delivery, correct?

23 MS. CARROLL: Objection. Form.
24 The witness may answer.

25 A. And, again, it looks -- yeah, there

1 appears to be some monitoring of the Vocollect
2 activity by the computer.

3 Q. Wasn't the Vocollect system back in
4 2009 sort of a state-of-the-art inventory
5 control system?

6 MS. CARROLL: Objection. Form.
7 Witness may answer.

8 A. I can't recall specifically.

9 Q. Well, can you recall anybody else
10 who you inspected who had a Vocollect system?

11 MS. CARROLL: Objection. Scope.
12 The witness is directed not to
13 answer.

14 MR. LIVINGSTON: Well, counsel, he
15 specifically mentions the Vocollect system. I
16 can explore why mentioning the Vocollect system
17 might be of some importance.

18 MS. CARROLL: I agree. Just don't
19 ask him about other inspections that he's done.

20 MR. LIVINGSTON: I'm not asking
21 about specific other inspections, just whether,
22 you know, based on -- you know, just as a
23 general matter whether he's aware of anyone
24 else who had the Vocollect system.

25 MS. CARROLL: Your question

1 previously went to inspections. If the
2 question is now is he aware of other
3 registrants who use such a system, then I think
4 that's within the scope. He may answer that
5 question if you want to ask that question.

6 Q. Are you aware of any other
7 registrant who either at the time or since has
8 installed a Vocollect system for inventory
9 control with respect to controlled substances?

10 A. I can't recall if any other
11 registrants have that system. I don't know.

12 Q. Would you go to the next page, 8, of
13 Exhibit 19? And there's a heading for Inventory
14 Controls. It says, "In addition to the
15 self-scan audit during selection," which I
16 presume was referring to the Vocollect system,
17 "HBC will perform random audits of at least 10
18 percent of the total tasks being completed.
19 After all selection is completed, HBC will cycle
20 count all controlled substances daily as the
21 business is run."

22 What does the DEA require with
23 respect to how often controlled substances must
24 be counted?

25 A. My understanding is that DEA

1 requires an initial inventory be taken that
2 would be upon the registrant's first handling
3 of controlled substances, then thereafter every
4 two years a physical inventory is required to
5 be completed. That's what I -- that's what
6 DEA, my understanding, refers to as a biennial
7 inventory.

8 Q. Okay. So once a registrant is up
9 and running, every two years they have to
10 count -- here it says that HBC is going to count
11 controlled substances daily. You would agree
12 that that's -- more than meets the minimal DEA
13 requirement for inventory?

14 A. Yes, with respect to the physical
15 inventory.

16 Q. And then if you go to the very
17 bottom, it talks about if there's any
18 discrepancies -- and after they do an
19 investigation -- "if discrepancies remain, the
20 HBC pharmacy merchandising team will be notified
21 and cycle count adjustments will be made. The
22 pharmacy merchandising group will notify all
23 customers to search for any discrepancy with
24 their inbound order."

25 And you understood that the

1 pharmacy merchandising group, that was at
2 corporate headquarters, correct?

3 A. I believe that was my
4 understanding.

5 Q. And so this is -- so this is telling
6 the reader that Giant Eagle's corporate office
7 was going to be watching the inventory of
8 controlled substances at HBC's facility?

9 MS. CARROLL: Objection. Form.
10 The witness may answer.

11 A. Yeah. My understanding is that
12 there would be oversight from their corporate,
13 which would include the pharmacy merchandising
14 team.

15 Q. Would you go to page 9 of this
16 report? It says, second paragraph, "As per 21
17 CFR 1301.74, the firm is responsible for
18 selecting a common or contract carrier which
19 provides adequate security to guard against in
20 transit losses." And then at the very bottom of
21 that paragraph it says, "As noted below, the
22 firm appears to comply with this cite."

23 So this -- again, you also found
24 that they -- that HBC was going to be
25 complying, based on what you were being told,

1 with 21 CFR 1301.74, correct?

2 A. Based upon my investigation, I
3 stand by that the firm appears to comply with
4 that cite.

5 Q. And the common carrier that was
6 selected is Prestige Delivery Systems, and you
7 actually went out to their -- visited their
8 facility to ensure that they would -- that they
9 complied with the regulation, correct?

10 A. Yes.

11 Q. And then if you go to page 11, at
12 the bottom it says, "On October 26, 2009, DI
13 Colosimo tested all aspects of the firm's
14 electronic security. The security was
15 operational and deemed adequate." So, you know,
16 with respect to electronic security, you gave
17 HBC a passing grade, correct?

18 A. Yeah, it was operational and
19 adequate.

20 Q. Now, when you do these
21 pre-registrant inspections, you know that a
22 number of folks are going to be relying on your
23 findings, correct?

24 A. What do you mean by that?

25 Q. Well, for example, I assume that you

1 have to report your findings to your group
2 supervisor, correct?

3 A. Yes.

4 Q. And he or she is going to rely on
5 the findings that you provide him or her,
6 correct?

7 A. That's my understanding.

8 Q. And, in addition, you're going to
9 report those findings to the registrant
10 applicant, correct?

11 A. What do you mean by that?

12 Q. Again, if you thought that there was
13 an issue or there was a problem with compliance,
14 you would want to let the registrant know so
15 that hopefully they can correct the problem,
16 correct?

17 A. Yes, that would be part of it.

18 Q. So -- and wouldn't it be -- wouldn't
19 you agree that it would be reasonable for the --
20 if you do your investigation and you have a
21 meeting with management and you say from
22 everything I've seen, you meet all of the
23 requirements, you're good to go, they should be
24 able to rely on what you're telling them, right,
25 that their systems, their security systems that

1 they have in place are at least adequate, if not
2 more than adequate, under the DEA regulations?

3 MS. CARROLL: Objection. Form.

4 The witness may answer.

5 A. I mean, insofar as what I'm able to
6 determine on that pre-registrant investigation,
7 I would agree with that.

8 - - - - -

9 (Thereupon, Defendants' Deposition
10 Exhibit 20, Report of Investigation
11 dated January 11, 2016, Beginning
12 Bates Stamp DEA-T1BCC-00001846, was
13 marked for purposes of
14 identification.)

15 - - - - -

16 Q. Would you turn to Exhibit 20, page
17 1? You see this is another report of
18 investigation by yourself, and it says, "Other
19 officers: Kurt Dittmer, RPS Patricia Robison,"
20 and "Kayla" -- I'm probably going to butcher the
21 name -- "Solonichne." Can you tell us what this
22 investigation -- which investigation this was
23 that you were involved in?

24 A. This was a pre-registrant
25 investigation of the Giant Eagle Rx

1 Distribution Center that proposed -- that
2 applied to open a distributor of Schedules 2
3 through 5 controlled substances in Freedom,
4 Pennsylvania.

5 Q. Was it your understanding that this
6 was a -- going to be a new warehouse for Giant
7 Eagle that was going to also distribute Schedule
8 2 controlled substances to Giant Eagle's own
9 pharmacies?

10 A. Yes, Schedules 2 through 5.

11 Q. Were you involved in any cyclic
12 investigations that the DEA performed on HBC
13 between 2009, when you did the pre-registrant
14 inspection, and the time of this investigation
15 of the proposed GERx facility in 2015?

16 A. I don't recall being involved with
17 any of those scheduled or cyclic
18 investigations.

19 Q. When you do a -- an investigation
20 like -- where there's a pre-registrant
21 investigation or a cyclic investigation, do you
22 talk to any of your colleagues who may have been
23 involved in other earlier investigations of the
24 registrant?

25 A. Sometimes I do that.

1 Q. And don't you usually try to note in
2 your report what the outcome of prior
3 investigations of that registrant have been, you
4 know, whether they passed or whether they had
5 issues or anything like that?

6 MS. CARROLL: Objection. Form.
7 The witness may answer.

8 A. We would include -- I would
9 personally include the results of any prior
10 inspections that took place.

11 MR. LIVINGSTON: I'd like to just
12 take a short restroom break, if that's okay
13 with everyone.

14 THE WITNESS: That's fine with me.

15 THE VIDEOGRAPHER: We're off the
16 record.

17 (Recess had.)

18 THE VIDEOGRAPHER: We're on the
19 record.

20 BY MR. LIVINGSTON:

21 Q. Mr. Colosimo, from time to time did
22 Giant Eagle ever ask you for any advice
23 regarding any of the security requirements
24 relating to controlled substances?

25 A. I believe after the -- after the

1 second Giant Eagle Rx Distribution Center
2 application was approved, I believe I did
3 contact them with -- or they -- one of the
4 Giant Eagle representatives contacted me
5 regarding some physical security aspect. I
6 can't recall specifically what that was, but I
7 think there was discussion about a physical
8 security issue.

9 Q. Okay. And did you provide any
10 guidance?

11 A. I can't recall specifically. Yeah,
12 I don't recall specifically, but I do remember
13 the request, but I can't remember what the
14 request was about.

15 Q. Okay. Well, let's turn back to
16 Exhibit 20, page 1, which was your investigation
17 report for the GERx facility before it opened.

18 Under the heading Subject Firm's
19 Background, you refer to the fact that HBC
20 currently -- you know, that currently, since
21 October of 2009, Giant Eagle's HBC facility was
22 a distributor of Schedule 3 through 5.

23 Do you see that?

24 A. Yes.

25 Q. And then below that you indicate

1 that "HBC has been the subject of three in-depth
2 cyclic investigations by the Pittsburgh D.O.,"
3 and then there's some redactions, but it says,
4 "None of which resulted in any administrative
5 actions."

6 So did you look back on those prior
7 in-depth cyclic investigations to see what the
8 outcome of those investigations was?

9 A. Yes.

10 Q. Do you remember which years those
11 cyclic investigations took place?

12 A. I believe the first one would have
13 been within a few years of the -- of their
14 approval. The others, I can't recall
15 specifically when those would have been.

16 Q. And did you just look at written
17 records of those prior investigations or did you
18 talk to the DEA folks who were involved in those
19 investigations or both?

20 A. I would have reviewed the written
21 file. I can't recall if I spoke with -- with
22 the investigators. I can't recall
23 specifically.

24 Q. Would you go to the next page? At
25 the very top it's talking about HBC. It says,

1 "The subject firm was the subject of in-depth
2 chemical regulatory cyclic investigations in
3 2002, 2004, 2008 and 2014. No violations were
4 uncovered during these investigations."

5 Now, you're referring here to the
6 List 1 chemical inspections; is that correct?

7 A. Yes.

8 Q. And, again, I mean, so -- when you
9 went out to the GERx facility to inspect it
10 before it opened, at that time you knew that
11 Giant Eagle's HBC facility had not had any
12 issues with respect to compliance with DEA
13 regulations during any of these audits going
14 back all the way to 2002, correct?

15 A. Could you ask that question again?

16 Q. Yes.

17 I mean, your report refers to every
18 single DEA inspection of HBC's facility, some
19 of which go back to 2002. You knew at the time
20 you went out to the GERx facility to check that
21 facility out before it opened that Giant
22 Eagle's HBC facility had essentially passed
23 every single inspection that the DEA had
24 conducted going all the way back to 2002?

25 MS. CARROLL: Objection. Form.

1 Mischaracterizes his statement.

2 Witness may answer.

3 A. I believe on page 1 of that report
4 I indicated that the three inspections of the
5 HBC facility did not result in any
6 administrative action, such as a letter of
7 admonition.

8 Q. Well, again, not to quibble, but you
9 reviewed those reports and one of those reports
10 was -- or a couple of those reports were
11 actually ones you authored, and all of those
12 reports indicated that there were no violations
13 discovered during those inspections going all
14 the way back to 2002, correct?

15 MS. CARROLL: Objection. Form.

16 The witness may answer.

17 A. You're distinguishing between the
18 controlled substance investigations that's
19 scheduled in the List 1 chemicals --

20 Q. I'm including both.

21 A. -- and as I indicated earlier, the
22 investigation of the controlled substance
23 facility, HBC, did not result in any
24 administrative action. I did not say that
25 there was not -- there were not issues that --

1 issues of concern that were not discussed
2 during -- during those scheduled
3 investigations, that there were no
4 administrative actions that were taken.

5 Q. I want to focus on compliance with
6 the regulations. You did not -- I mean, from
7 2002 until the time that you went out to the
8 GERx facility in 2015, the DEA had not found and
9 reported in any of its investigation reports
10 that Giant Eagle was in violation of any DEA
11 regulation?

12 A. There was no -- and, again, there
13 was no administrative action that was cited, a
14 formal administrative action in any of these
15 facilities.

16 Q. I understand that, but we're both
17 reading the same report, aren't we? It says,
18 "No violations were uncovered during these
19 investigations," and we know from the prior
20 investigation report, before HBC opened, that
21 you yourself performed or wrote that you noted
22 that there had been no prior violations before
23 and you found none in your investigation,
24 correct?

25 A. And, again, I want to make -- the

1 report I think is clear that when I say "No
2 violations were uncovered during these
3 investigations," I'm addressing the List 1
4 chemicals, the Schedule -- the -- the
5 controlled -- the HBC with the controlled
6 substances, I'm saying there's no
7 administrative actions -- formal administrative
8 actions were taken.

9 Q. Let me ask you this: You
10 recommended in 2009 that the DEA approve Giant
11 Eagle's/HBC's request for a Schedule 3 license,
12 correct?

13 A. They were approved. I authored the
14 report approving that application with the
15 approval of my supervisor.

16 Q. You would never recommend that an
17 applicant's request for a DEA controlled
18 substance license be approved if you thought
19 they were going to be violating any of DEA's
20 security requirements?

21 MS. CARROLL: Objection. Form.
22 The witness may answer.

23 A. I would not approve it if I believe
24 that they were not going to be compliant or
25 assured us that they were not going to be

1 compliant with DEA regulations.

2 Q. For example, if they showed you the
3 plans for their cage and the cage didn't meet
4 DEA's requirements, you're not going to
5 recommend approving that application unless they
6 fix that problem, correct?

7 A. Correct.

8 Q. So can't we conclude that your
9 understanding was that everything that Giant
10 Eagle proposed to do at its HBC facility was
11 going to be in compliance with the security
12 requirements?

13 A. What they proposed to do, what they
14 assured me, assured DEA that they were going to
15 do would be in compliance, and based upon that,
16 the application was approved.

17 Q. All right. Let's go back to Exhibit
18 20, which was your report relating to the GERx
19 facility from 2015. Let me just ask a question
20 a little bit differently. Again, you referred
21 to these past reports on HBC's facilities that
22 you reviewed. You did not see in any of those
23 reports any indication that Giant Eagle was in
24 violation of any of the security requirements
25 under the Controlled Substance Act, correct?

1 A. Again, as I mentioned earlier,
2 there were no administrative actions taken. I
3 put that in my report. But there were issues
4 that -- that I wanted to address in my -- in my
5 review of the application for the facility in
6 Freedom, Pennsylvania.

7 Q. I'm sorry. I'm not sure I followed
8 what you said. What issues are you referring
9 to?

10 A. That issue would be with the
11 suspicious orders program, suspicious orders
12 and monitoring system.

13 Q. And you're talking about when you
14 went out to GERx in 2015?

15 A. Yes.

16 Q. And you said you had concerns after
17 your -- when you were preparing your report in
18 2015 with respect to the suspicious order
19 monitoring system?

20 A. I said the concerns were expressed
21 in the reports of the HBC facility.

22 Q. Oh, I see. The prior reports?

23 A. Yes.

24 Q. Okay. Okay. I gotcha. So let's
25 turn to the next page, or page 2 of Exhibit 20.

1 In the middle of the page you say that "Over the
2 past several years, McKesson Drug, a distributor
3 in New Castle, has been the primary supplier of
4 Schedule 2 controlled substances to the Giant
5 Eagle pharmacies." I don't want to ask you any
6 questions about your inspections of McKesson,
7 but just that as a distributor of Schedule 2
8 controlled substances, the McKesson facility in
9 New Castle, like Giant Eagle, would have had to,
10 in order to maintain its license, be subject to
11 cyclic investigations that were checking to make
12 sure it had an adequate SOM system, correct?

13 A. Yes.

14 Q. And then we see a reference to Mr.
15 Shaheen, so at least by 2015 Mr. Shaheen was on
16 board at Giant Eagle, correct?

17 A. Correct.

18 Q. It says that Mr. Shaheen notified
19 Mr. Dittmer and also John Conlon that Giant
20 Eagle was considering adding a cage and a vault
21 to an existing warehouse owned by the company in
22 Freedom, PA, where they would be able to
23 distribute 2 through 5 controlled substances,
24 and that was in the summer of 2015. Was
25 Mr. Conlon involved in any prior inspections of

1 Giant Eagle's facilities?

2 A. Yes.

3 Q. If you go to the next paragraph, it
4 says that, "On October 1, 2015, GERx was granted
5 a license with the Pennsylvania Department of
6 Health as a distributor."

7 Do you see that?

8 A. Yes.

9 Q. Why is that information noted?

10 A. Because the DEA registration for
11 the distributor application could not be
12 granted until there was proper state licensure
13 by that facility.

14 Q. And you did an on-site inspection,
15 correct?

16 A. Yes.

17 Q. Go to page 3. And you see in the
18 middle of the page it talks about how you
19 provided Giant Eagle with the relevant
20 regulations that apply to the distribution of
21 controlled substances, which included the
22 suspicious order regulation; is that correct?

23 A. Yes.

24 Q. If you go to the next page, 4, under
25 the heading Record Keeping, second paragraph, it

1 says, "As noted above, prior cyclic
2 investigations conducted at HBC have not
3 resulted in any administrative actions. HBC was
4 the subject of its first regulatory
5 inspection/cyclic investigation in May 2011, and
6 documented under DEA file number," which is left
7 blank. "The result of this investigation
8 revealed minor recordkeeping violations (an
9 overage due to computer software malfunction)."
10 And "This issue was resolved on-site."

11 Do you see that?

12 A. Yes.

13 Q. The reference to "This issue was
14 resolved on-site," meaning that there was -- it
15 was not considered to be a real violation, that
16 it was just a software malfunction and it was
17 resolved at the time?

18 MS. CARROLL: Objection. Form.

19 Witness may answer.

20 A. That did not result in a formal
21 administrative action. That issue was resolved
22 on-site and I included that in my report.

23 Q. And you reviewed this May -- did you
24 review this May 2011 investigation report?

25 A. Yes.

1 Q. And then under the heading ARCOS --
2 and just for the jury's benefit, ARCOS is a
3 system whereby all distributors have to report
4 every sale of a controlled substance to the DEA,
5 correct?

6 A. Yes, that would be part of their
7 responsibilities under that regulation.

8 Q. And at the very bottom it says, "A
9 review of HBC's ARCOS history revealed all
10 required reports were filed in a timely manner
11 with no delinquencies," correct?

12 A. Yes.

13 Q. If you go to page 5, and under
14 Theft/Loss, it indicates that you notified Giant
15 Eagle personnel of the requirement to notify the
16 DEA upon discovery of any theft or significant
17 loss of a controlled substance, and then it
18 looks like you reviewed the file and you found
19 that HBC had filed four DEA Form 106s. And 106,
20 is that the official DEA form for reporting a
21 loss?

22 A. Yes.

23 Q. And there was only four that were
24 filed. Did that -- is that considered average,
25 above average, below average in terms of theft?

1 A. Yeah, I don't know if -- how that
2 compares to other distributors during that --
3 during a similar period of time.

4 Q. So then you specifically go through
5 each one and you say, "One loss was attributed
6 to employee pilferage. His employment was
7 terminated. Three were described as in-transit
8 losses." If it's an in-transit loss, then it's
9 not -- it's not the fault of HBC, if it arrives
10 at the facility and it's already been stolen,
11 right?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. My understanding is that the
15 obligation is upon the distributor if it's lost
16 in transit from the distributor to the
17 customer, in which case it would be the
18 pharmacy.

19 Q. And it says, "HBC appropriately
20 documented on each of the forms security
21 measures they took to prevent or limit future
22 thefts/losses." So you were comfortable that
23 Giant Eagle was doing what it needed to do to
24 prevent theft and loss, correct?

25 MS. CARROLL: Object to form.

1 Witness may answer.

2 A. In my report I indicated that they
3 appeared to handle those thefts in the
4 appropriate -- appropriate manner, with the
5 proper recordkeeping.

6 Q. Would you go to page 7 of this
7 report? We're not going to bore the jury with
8 all the various specifications that the DEA has
9 for cages, but just I wanted to focus your
10 attention on the fact that Giant Eagle's
11 proposed GERx cage met, in your view, all of the
12 requirements in 21 CFR 1301.72(b)(4), correct?

13 A. Yes.

14 Q. And then you also closely examined
15 the vault specifications, and the vault door
16 alone was going to weigh over 4,000 pounds,
17 right? That's indicated at the next page at the
18 top.

19 A. Yes.

20 Q. And then you said in the next
21 paragraph, "Almost all elements of the vault and
22 vault door appeared to meet the requirements
23 specified in 21 CFR 1301.72." And then you say,
24 "However, while the vault's day gate was
25 equipped with a contact switch, the vault door

1 was not equipped as such as required by the
2 regulation."

3 Rick Shaheen followed up on this
4 concern right away and that issue was fixed
5 promptly, wasn't it?

6 A. I believe so, yes.

7 Q. In fact, you seem to note that in
8 the next paragraph. You say, "After the on-site
9 visit, the Pittsburgh D.O. received confirmation
10 that a contact switch was installed on the front
11 door on December 17, 2015."

12 Do you see that?

13 A. Yes.

14 Q. So that was -- so Giant Eagle very
15 quickly responded to your concern, correct?

16 A. Yes.

17 MS. CARROLL: Objection. Form.

18 Withdrawn.

19 Q. If you go to page 9 of your report,
20 at the very top it talks about, "All controlled
21 substances will be stored in a secure cage or
22 vault fully described elsewhere in this report.
23 As outlined in the attached 'Inventory Control -
24 Suspected Loss Policy' - all generic controlled
25 substances are cycle counted two times per week,

1 while name brand controlled substances are
2 counted nightly after selection is completed."
3 And, again, this is a much more frequent
4 counting of controlled substances inventory than
5 is required by the DEA regulations, correct?

6 MS. CARROLL: Objection. Form.
7 The witness may answer.

8 A. As I testified earlier, DEA
9 requires the initial inventory, you know, upon
10 registration or first handling, and then
11 thereafter two years of physical count is
12 required. It's the biennial inventory.

13 Q. Right. That's the minimum
14 requirement, correct, but Giant Eagle counts
15 much more frequently than that?

16 A. As represented in their policy.

17 Q. Right. I mean, as somebody who has
18 devoted his life to helping stop diversion, you
19 would rather see Giant Eagle and other
20 distributors counting their inventory nightly
21 than once every two years, right?

22 MS. CARROLL: Objection. Form.
23 The witness may answer.

24 A. The biennial inventory is the
25 minimal once every two years. Personally, in

1 my experience, I recommend more frequent, more
2 routine physical counting to eliminate or to
3 mitigate against diversion.

4 Q. Would you go to page 10 of your
5 report under the heading Due Diligence? It
6 says, "Because the supplier (GERxDC) and
7 customers (Giant Eagle pharmacies) are owned by
8 Giant Eagle Inc., GERxDC will have access to
9 customer information that will assist them in
10 enacting the following 'due diligence' actions."

11 Again, so it was your understanding
12 that Giant Eagle, because it was only
13 distributing to its own customers, would have
14 very in-depth information relating to its
15 customers?

16 A. Well, that they would have -- that
17 they would have dispensing ordering information
18 for their -- for their customers, prescription
19 information.

20 Q. Well, let's just take some for
21 examples. They would know if, for example, a
22 competitor pharmacy across the street either
23 just opened or just closed, right, which might
24 affect how much prescriptions they would end up
25 needing to fill?

1 MS. CARROLL: Objection. Form.

2 Witness may answer.

3 A. I don't know. You would have -- I
4 would have to ask that pharmacy, that, you
5 know, representative in their headquarters if
6 they knew about that specifically. I don't
7 know. I'd be speculating as to what they would
8 know.

9 Q. But you do think it's important to
10 note this information in your reports, correct?

11 A. Which information is that?

12 Q. The fact that Giant Eagle's only
13 customers for its GERx facility were its
14 pharmacies.

15 A. Yes. It's important to put in
16 there.

17 Q. If you go down to under Customer
18 Authentication, the paragraph in the middle, it
19 says, "The GERxDC only services Giant Eagle
20 pharmacies which are owned by Giant Eagle, Inc.
21 If, for any reason, a Giant Eagle pharmacy is
22 not licensed to receive Legend drug products or
23 controlled substances, the GERxDC will no longer
24 service the pharmacy."

25 Now, you understood from this that

1 Giant Eagle, again, was going to be monitoring
2 its own pharmacies to make sure that they were
3 at all times -- that they at all times had a
4 current DEA license, and if for some reason
5 they didn't, GERx would immediately stop
6 shipping controlled substances to that
7 pharmacy, correct?

8 A. That's what I stated in my report.
9 That's my understanding.

10 Q. Then on the next page, 11, there's a
11 section called -- a whole section on Suspicious
12 Orders, correct?

13 A. Yes.

14 Q. Okay. And we're not going -- for
15 time reasons, we're not going to go through this
16 whole thing -- it goes on for a few pages -- but
17 you ultimately concluded that the proposed
18 suspicious order system was -- that it would be
19 compliant with DEA regulations?

20 A. In my report I described the system
21 as represented to me by Giant Eagle. I did not
22 evaluate its effectiveness. I just -- I
23 completely described it as they represented to
24 me in -- with the handout that they gave me.

25 Q. I'm just -- I mean, at the end --

1 well, would you have approved or recommended
2 approval of this application if you thought that
3 the SOM system that -- as described to you by
4 Giant Eagle, would not comply with DEA
5 regulations?

6 MS. CARROLL: Objection.

7 A. With regard to their suspicious
8 order policy, I provided them with the CFR cite
9 and the emphasis is on their responsibility to
10 design and operate a system. I did not
11 evaluate the system. I described the system.
12 They were representing that this is what they
13 would have in place for their suspicious order
14 system specifically with regard to assuring me
15 that that system would detect the -- by size,
16 frequency of report, frequency of orders or
17 anything suspicious, unusual frequency of those
18 orders.

19 Q. At the time that you went out to the
20 GERx facility in late 2015, at that time HBC
21 still had an active Schedule 3 license and was
22 still distributing Schedule 3 drugs to its
23 own -- to Giant Eagle's own pharmacies, correct?

24 A. I believe they were, yes.

25 Q. And that HBC's suspicious -- that

1 DEA had not found anything wrong with HBC's then
2 existing SOM system; is that correct?

3 A. As I indicated earlier, there was
4 no administrative action to indicate that the
5 system was delinquent or deficient.

6 Q. Well, if the DEA knew that Giant
7 Eagle's HBC suspicious order monitoring system
8 was deficient, that the system as described to
9 the DEA did not meet DEA regulations, it would
10 have taken administrative action or done
11 something about it, correct?

12 MS. CARROLL: Objection to form.
13 The witness may answer.

14 A. Repeat the question.

15 Q. Yes. I think it's important for the
16 jury to understand what it means when the DEA
17 inspects a facility and says that your
18 suspicious order monitoring system is fine. So
19 we know from the inspection reports that you've
20 looked at that the DEA regularly inspected HBC's
21 facilities, including its suspicious order
22 monitoring system, and that the DEA, as you like
23 to say, never took any administrative action
24 with respect to that system, correct?

25 MR. MOUGEY: Objection.

1 A. Administrative action was not taken
2 during any of those three scheduled
3 investigations of HBC.

4 Q. Right. And now for the jury's
5 benefit, and I think they need to understand
6 what that means, if, in fact, the DEA found
7 anything wrong with Giant Eagle's/HBC's
8 suspicious order monitoring system on any of its
9 inspections, it would either require Giant Eagle
10 to get into compliance or it would take
11 administrative action, wouldn't it?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. I'm talking -- I could answer
15 personally. I was not involved with those
16 three inspections of the HBC facility.

17 Q. I know you weren't, but you looked
18 at them. You looked at the reports.

19 A. Yes.

20 Q. Okay. And we already know that no
21 administrative action was taken because you
22 specifically noted it in your GERx report,
23 correct?

24 A. Yes.

25 Q. So my only question here is, isn't

1 it true that whether it's you or one of your
2 colleagues, when you inspect a distributor's
3 facility, if their SOM system is non-compliant,
4 that you're not just going to let it go, you're
5 either going to require the registrant to
6 comply, or if they don't comply, you're going to
7 take administrative or some other action against
8 the facility, correct?

9 MS. CARROLL: Objection. Form.

10 The witness may answer.

11 A. There's a difference between -- and
12 this is my experience. There's a difference
13 between saying that this monitoring system does
14 not comply and suggestions to have a more
15 formal system in place.

16 Q. Right. And I'm talking about in the
17 situation where the system does not comply.
18 Then you're going to do something about that,
19 right? You're going to try to get the
20 registrant to comply, or I suppose if they're
21 really, you know, difficult and they don't
22 comply, that you're going to take some sort of
23 action against them?

24 MS. CARROLL: Objection. Form.

25 Q. It just seems like it's common

1 sense.

2 MR. MOUGEY: Objection.

3 Q. I mean, if I'm wrong about that,
4 please let me know.

5 MS. CARROLL: Objection.

6 Witness may answer.

7 A. There was a series of questions
8 that you asked there.

9 Q. I was trying to just explain the one
10 question that I asked, but maybe I'll try it
11 again. Isn't it true that if an applicant has a
12 SOM system that the DEA knows does not comply
13 with the regulations, that either they're going
14 to require the applicant to comply, or if the
15 applicant is adamant and won't comply, the DEA
16 will take some sort of administrative or other
17 action against the applicant or registrant?

18 MS. CARROLL: Objection to form.

19 The witness may answer.

20 A. In my experience, I would take
21 administrative action and ensure that there was
22 compliance. That would be corrected on-site.

23 Q. So can't we rest assured that at the
24 time you went out to GERxDC in 2015, that HBC's
25 SOM system was viewed by the DEA at that time as

1 being in compliance with the security
2 requirements?

3 MR. MOUGEY: Objection.

4 THE COURT REPORTER: Excuse me. I
5 need to know the male voice that's objecting.

6 MR. MOUGEY: Pete Mougey.

7 MS. CARROLL: Mr. Colosimo, would
8 you like Mr. Livingston to repeat the question?

9 THE WITNESS: Please.

10 Q. Yes. I mean, can we all rest
11 assured that from the DEA's perspective, Giant
12 Eagle's HBC facility was in compliance with the
13 SOM regulation when you went out to GERxDC in
14 2015?

15 MR. MOUGEY: Objection.

16 A. When I visited the Giant Eagle
17 facility in Freedom, I reviewed the -- they
18 presented me with their ordering monitoring
19 system that they were going to be enacting for
20 the Giant Eagle facility in Freedom. I did not
21 review the HBC facility SOM.

22 Q. If you look at page 12, at the very
23 bottom it says, "Richard Shaheen, pharmacy
24 investigator, described a few other steps Giant
25 Eagle has taken to limit the potential for

1 diversion occurring within their pharmacies:
2 All Giant Eagle pharmacists have received
3 training on procedures for checking in
4 controlled substance orders; these procedures
5 will assist in the prevention and detection of
6 in-transit losses. While all Giant Eagle
7 pharmacies are required to conduct monthly
8 accountability audits, the pharmacist assigned
9 to complete these audits vary from month to
10 month."

11 So isn't it true that Giant Eagle
12 had some controls also at the pharmacy level
13 and not just at the HBC level to try to prevent
14 diversion?

15 MS. CARROLL: Objection to form.

16 The witness may answer.

17 A. That's my understanding, that they
18 did have procedures in place to limit diversion
19 at the pharmacy level.

20 Q. And then we've already talked about
21 at the corporate level they also oversaw all of
22 the sales and the inventory relating to both the
23 pharmacies and HBC as another control against
24 diversion, correct?

25 MS. CARROLL: Objection to form.

1 The witness can answer.

2 A. My understanding is that there was
3 oversight of the warehouse by -- at the
4 corporate level by Giant Eagle.

5 - - - - -

6 (Thereupon, Defendants' Deposition
7 Exhibit 3, Reports of Investigation
8 Beginning Bates Stamp
9 US-DEA-00033016, was marked for
10 purposes of identification.)

11 - - - - -

12 Q. Would you turn to Exhibit 3, page 9?
13 Do you see that this is a report of
14 investigation by Michael Kupchick from your
15 office and it was prepared on May 20, 2011? Is
16 this one of the investigation reports of HBC's
17 facility that you reviewed?

18 A. Yes.

19 Q. And it says -- this was a cyclic
20 investigation, correct?

21 A. Yes.

22 Q. And it says that Mr. Kupchick had
23 some assistance from Vincent Tomei from your
24 office as well?

25 A. Yes.

1 Q. You would agree that both of those
2 individuals are very competent and highly
3 dedicated DEA inspectors, correct?

4 A. I work with both Investigator
5 Kupchick and Investigator Tomei.

6 Q. And they're both competent and
7 conscientious, correct?

8 MS. CARROLL: Objection to form.
9 The witness may answer.

10 A. I'm not the supervisor of either of
11 those investigators.

12 Q. Well, do you trust their work? I
13 mean, do you trust their work?

14 A. What do you mean by that?

15 Q. Well, you reviewed this work product
16 that they produced, this report, and you seem to
17 rely on it at least to some extent. Did you
18 trust the accuracy of the report when you
19 reviewed it?

20 A. The accuracy of the report?

21 Q. Yes.

22 A. I don't recall that there was
23 anything in there that I disagreed with that
24 was not accurate.

25 Q. A little further down it says, "This

1 investigation revealed no discrepancies with
2 respect to security." The security regulations
3 include the SOM regulation, correct?

4 MS. CARROLL: Objection.

5 A. This is not my report. This is
6 Investigator Kupchick's report.

7 Q. Right, I know, but you read the
8 report. And what did you understand this
9 reference to be referring -- to mean, "This
10 investigation revealed no discrepancies with
11 respect to security"?

12 A. After reading the report, and this
13 is my perspective, no discrepancies with regard
14 to physical security at the facility, at the
15 warehouse.

16 Q. Was it your understanding that at
17 this time HBC was still using the Vocollect scan
18 system for inventory control?

19 A. I don't know if that was mentioned
20 in this report.

21 Q. Why don't you go to page 19. At the
22 top it says, "All selections are performed using
23 Vocollect directed activity." Does that refresh
24 your recollection that in 2011 HBC was still
25 using the Vocollect system?

1 A. Yes.

2 Q. What does the report mean when it
3 says "no discrepancies"? Is that the same as no
4 violations? What does that mean?

5 MS. CARROLL: Objection. Form.
6 Witness may answer.

7 A. I don't -- I'm not sure of the
8 distinction. In my opinion, the violation
9 would be something that would rise to the
10 issuance of a formal administrative letter or
11 administrative action. The discrepancy could
12 be -- and, again, this is my perspective,
13 discrepancy could be some issue that was
14 resolved on-site where it did not rise to the
15 level of an administrative action.

16 Q. In your mind, the violation is more
17 serious than just a discrepancy, which is a very
18 minor issue, correct?

19 MS. CARROLL: Objection. Form.
20 The witness may answer.

21 A. They would be both issues that need
22 to be resolved in my perspective.

23 Q. Could you go to page 40, please?
24 This is a report of investigation by John Conlon
25 from your office prepared August 13, 2013

1 relating to the HBC facility. Did you review
2 this report?

3 A. Yes.

4 Q. And then at the very bottom of the
5 synopsis on the first page, it says, "This
6 investigation revealed no discrepancies with
7 respect to recordkeeping or security."

8 Do you see that?

9 A. Yes.

10 Q. So this -- again, we have another
11 indication here that HBC essentially has a clean
12 inspection report, correct?

13 MS. CARROLL: Objection. Form.
14 The witness may answer.

15 A. That's what Investigator Conlon
16 indicated, no discrepancies with respect to
17 recordkeeping or security.

18 Q. And this report would have also, as
19 part of this -- of the inspection, would have
20 looked at HBC's SOM system at the time, correct?

21 A. I believe this did.

22 Q. Would you go to page 42? The
23 heading is "Subject Firm's Background. At the
24 very bottom of that first paragraph it says,
25 "HBC Service Company had 157 million dollars in

1 sales during 2012, of which controlled
2 substances accounted for less than one percent."

3 Why is that fact noted here or why
4 would that fact be noted here?

5 MS. CARROLL: Objection. Form.

6 The witness may answer.

7 A. That is part of the subject firm's
8 background and that's what Investigator Conlon
9 put in his report as -- to provide additional
10 details about the firm's background.

11 Q. Is one percent of sales involving
12 controlled substances, is that low or high or
13 average for a distributor in your experience?

14 MS. CARROLL: Objection. Form.

15 The witness may answer.

16 A. I don't know if that's low or high.

17 Q. So it's important to note it, but
18 nobody knows what the significance of it is,
19 whether that really means anything, one percent?

20 MS. CARROLL: Objection. Form.

21 The witness may answer.

22 Q. You see on the next page, 47, under
23 Sales/Distribution Records, at the bottom it
24 says, "These records were maintained in
25 accordance with requirements set forth in Title

1 21 CFR 1304.22(b)." 2

3 Do you see that?

4 A. What page are you looking at?

5 Q. Page 47 under the heading
6 Sales/Distribution Records. If you look in the
7 screen, you can see --

8 A. That's what's in the report,
9 correct.

10 Q. And there was no discrepancies noted
11 on the next page with respect to ARCOS and/or on
12 page 49 with respect to the cage requirements,
13 everything was in compliance with respect to
14 these issues, correct?

15 MS. CARROLL: Objection. Form.
16 The witness may answer.

17 A. I see for the section on ARCOS it
18 said no discrepancies were noted.

19 Q. All right. So would you go -- skip
20 ahead to page 52 under the heading Due
21 Diligence. And do you see that Mr. Rogos from
22 HBC advised the DEA that, unlike other drug
23 distributorships, HBC has only one customer,
24 Giant Eagle. And that's consistent with your
25 understanding as well, right, that Giant
Eagle's -- the only customer for its

1 distribution facilities are its own pharmacies,
2 correct?

3 MS. CARROLL: Objection. Form.
4 The witness may answer.

5 A. That's my understanding, yes.

6 Q. And then the report notes a
7 conversation that Mr. Conlon had with Mr. Rogos
8 about referring Mr. Rogos to the suspicious
9 order monitoring regulation, correct?

10 A. Yes.

11 Q. And then Mr. Rogos told Mr. Conlon
12 at this time HBC and/or Giant Eagle, Inc. and
13 its parent company has no computerized software
14 system to indicate that an order may be
15 suspicious. Rogos advised that if Giant Eagle
16 pharmacy were to receive unusually high orders
17 of controlled substances from HBC deviating from
18 other stores, it would be noticed at the Giant
19 Eagle, Inc. headquarters level. Rogos stated
20 that he will bring this issue to the attention
21 of Greg Carlson and Kim Remas of Giant Eagle's
22 headquarters controlled substance purchasing
23 unit.

24 Do you see that?

25 A. Yes.

1 Q. Okay. So is it your understanding
2 that essentially the DEA is saying, hey, you
3 know, you've been in compliance with the reg but
4 we think you can improve it possibly by going to
5 an automated system, right? Was that your
6 understanding of what was being suggested to
7 Giant Eagle at this time?

8 MS. CARROLL: Objection. Form.
9 The witness may answer.

10 MR. MOUGEY: Objection.

11 A. That's -- my understanding is that
12 the DI Investigator Conlon made suggestions,
13 noted that there was no computerized system to
14 detect that and made a suggestion to Mr. Rogos
15 to have that implemented.

16 Q. If you go to the next page, 53,
17 under Meeting with Management, it says, "During
18 this meeting, investigators advised Rogos that
19 both recordkeeping and security are in full
20 compliance with the requirement set forth in
21 Title 21 Code of Federal Regulations."

22 That includes the SOM regulation,
23 correct?

24 MS. CARROLL: Objection. Form.
25 Witness may answer.

1 A. The SOM regulation, I mean, insofar
2 as that is under security, that's accurate.

3 Q. So he says that, Giant Eagle, you're
4 in full compliance, tells Giant Eagle you're in
5 full compliance with all the security regs,
6 including the SOM regs, but then he says, but,
7 you know, I advised Mr. Rogos to develop a
8 better system of due diligence, correct? So
9 he's saying we think you can improve your
10 system, here's our advice, and then Mr. Rogos
11 said he would follow up, correct?

12 MS. CARROLL: Objection. Form.
13 The witness may answer.

14 A. Those are your words. I'll read
15 it. "Investigator Conlon advised Rogos to
16 develop a better system of due diligence,"
17 period.

18 Q. Right after he told Mr. Rogos, and I
19 assume he was being a hundred percent honest,
20 that Giant Eagle, with all of the security
21 requirements, which, of course, includes the SOM
22 requirement, correct?

23 MS. CARROLL: Objection. Form.
24 The witness may answer.

25 A. And, again, my understanding is

1 that the suspicious orders would fall under
2 security.

3 Q. Let's take a look at to see if Giant
4 Eagle tried to follow up with what Mr. Conlon
5 had recommended.

6 - - - - -

7 (Thereupon, Defendants' Deposition
8 Exhibit 16, E-Mail String Beginning
9 Bates Stamp HBC_MDL00136952, was
10 marked for purposes of
11 identification.)

12 - - - - -

13 Q. Would you go to Exhibit 16? Just
14 for reference, we were just looking at the
15 report from August of 2013. You see Exhibit 16
16 is an e-mail from Joseph Millward at Giant Eagle
17 to some other folks at Giant Eagle dated
18 November 14, 2013 regarding daily HBC suspicious
19 purchasing report.

20 Do you see that?

21 A. Yes.

22 Q. If you skip down to the bottom, this
23 is an e-mail response to another e-mail from
24 Kayla Voelker at Giant Eagle, and she says, "We
25 had two pharmacies exceed the purchasing

1 thresholds of certain controlled products so far
2 this month." So do you see that Giant Eagle a
3 few months later already had the automated
4 threshold system in place for suspicious order
5 monitoring?

6 MS. CARROLL: Objection. Form.
7 The witness may answer.

8 A. I don't know what they had in
9 place. This is an e-mail that you're referring
10 to that addresses thresholds.

11 Q. Right. Which is what an automated
12 threshold system does, right? It has --
13 automatically when you hit a certain threshold
14 at a store for purchasing a certain item, it's
15 flagged, right?

16 MS. CARROLL: Objection. Form.
17 The witness may answer.

18 A. I'm familiar with the term
19 "threshold," but I don't know what Giant Eagle
20 had in place at this time to detect that.

21 Q. Hasn't Giant Eagle -- didn't Giant
22 Eagle report some suspicious orders to you
23 telephonically or by e-mail?

24 MS. CARROLL: Objection. Form.
25 Vague.

1 The witness may answer.

2 A. I guess I don't know. Is it to me
3 personally or to DEA, the Pittsburgh district
4 office or DEA in general?

5 Q. Well, to you. Do you remember ever
6 getting any report from Giant Eagle, hey, we
7 flagged this suspicious order of a particular
8 controlled substance?

9 MS. CARROLL: Objection. Form.
10 Witness may answer.

11 A. I don't know.

12 - - - - -

13 (Thereupon, Defendants' Deposition
14 Exhibit 12, E-Mail String,
15 Beginning Bates Stamp
16 HBC_MDL00132815, was marked for
17 purposes of identification.)

18 - - - - -

19 Q. Why don't we go to Exhibit 12. This
20 is an e-mail from Mr. Millward to some other
21 folks at Giant Eagle, including Mr. Shaheen, and
22 it's dated December 5, 2013, and it says, "Team,
23 to update the group, Mike e-mailed and called
24 HBC to inform them that 2401 flagged on the
25 order monitoring report. The follow-up

1 uncovered an unusual pattern of prescriptions
2 for buprenorphine that requires deeper
3 investigation."

4 Doesn't this confirm for you that
5 Giant Eagle had an automated threshold system
6 in place for its SOM system by the end of 2013?

7 MS. CARROLL: Objection. Form.

8 The witness may answer.

9 A. I don't know what they had in
10 place. This is an e-mail where they're
11 referencing an unusual pattern of prescriptions
12 for buprenorphine.

13 Q. Well, there's a number of bulleted
14 items in the middle of this e-mail, and at the
15 very bottom he says, "I called and left a voice
16 mail with DEA Diversion Investigator Lou
17 Colosimo to report the suspicious order."

18 Does that refresh your recollection
19 that at the end of 2013 Giant Eagle had begun
20 reporting suspicious orders flagged by its
21 threshold system to you?

22 MS. CARROLL: Objection. Form.

23 Misstates the document.

24 You may answer.

25 A. That's what's represented in the

1 e-mail. I don't recall that voice mail. I
2 don't recall -- I don't know what particular
3 pharmacy they're referencing there. I don't
4 recall that voice mail.

5 Q. At the very bottom he says, "We will
6 continue to discuss this in detail tomorrow.
7 The HBC orders will be held until I approve them
8 to resume."

9 From what you're seeing in this
10 report, you would agree that Giant Eagle is
11 doing the appropriate thing when there's an
12 unusual pattern of orders relating to a
13 controlled substance, they're stopping the
14 order and they're investigating it and not
15 letting it go through without investigation,
16 correct?

17 MR. MOUGEY: Objection.

18 MS. CARROLL: Objection. Form.

19 The witness may answer.

20 A. I don't know everything that
21 they're doing here. I don't know that I was
22 notified. This is in an e-mail that's -- from
23 my perspective, it's addressed to other Giant
24 Eagle personnel, so I don't know if this is
25 sufficient or not.

1 Q. Go to the next page. At the very
2 end he says, "We will be taking a two pronged
3 approach for this order: Stopping the shipment
4 of the order and reporting it to the DEA as well
5 as having a corporate staff member investigate
6 the usage and determine the causation of the
7 suspicious order."

8 I mean, somebody with -- you know,
9 given your background with enforcing DEA
10 regulations, is there anything else that Giant
11 Eagle should have been doing in light of the
12 situation that's presented in this exhibit;
13 they're stopping the order, they're
14 investigating it, they're reporting it to the
15 DEA, and they're having someone from corporate
16 do the investigation? Is there anything that
17 you can think of else that Giant Eagle should
18 have been doing in this situation?

19 MR. MOUGEY: Objection.

20 MS. CARROLL: Objection. Form.

21 The witness may answer.

22 A. This is a general e-mail about a
23 specific store. It does not specifically
24 mention quantities. I don't know what -- what
25 else -- what other information Giant Eagle had

1 access to that would affect what decision that
2 they were making -- should be making on that
3 particular order. I know that they are
4 required to report once they determine it's
5 suspicious, to notify DEA.

6 Q. Do you keep a record of -- like if
7 Giant Eagle had left you a voice mail reporting
8 an order, do you make a record of that anywhere?

9 A. I don't recall receiving any voice
10 mails or oral notifications from any
11 distributor about a suspicious order. I don't
12 recall this incident.

13 Q. So you ultimately approved Giant
14 Eagle's application or recommended -- I'm
15 sorry -- approval of Giant Eagle's application
16 for GERxDC to get a Schedule 2 license, correct?

17 A. In working with our supervisor,
18 Kurt Dittmer, it was approved.

19 Q. Were you involved in the 2017 cyclic
20 investigation of the GERxDC facility?

21 A. No, not the on-site inspection.

22 Q. You have no knowledge about that
23 on-site investigation?

24 A. No, I was not involved with the
25 on-site. I was not on-site for that

1 investigation.

2 Q. But you were involved in that
3 investigation, the 2017 cyclic investigation of
4 GERxDC?

5 A. I reviewed --

6 MS. CARROLL: Objection. Form.

7 A. I reviewed a report that
8 Investigator Kupchick completed for that
9 inspection.

10 Q. And he found no discrepancies or
11 violations, correct?

12 MS. CARROLL: Objection. Form.

13 The witness may answer.

14 A. I know there was no -- nothing
15 administrative -- I'd have to look at the
16 report.

17 Q. Why don't you do that now. It's on
18 Exhibit 3, page 79. It's dated May 26, 2017.
19 You approved this report, correct? You signed
20 it, signed off as --

21 A. Yeah. On that date I was the
22 acting diversion supervisor. We were without a
23 permanent or full-time supervisor.

24 Q. Okay. And you were -- reviewed this
25 report before you approved it, correct?

1 A. I reviewed this report among others
2 before it was approved.

3 Q. And the report concludes that --
4 says, "This investigation revealed no
5 discrepancies with respect to recordkeeping or
6 security," correct?

7 A. Yes.

8 Q. And that would have included no
9 discrepancies with respect to Giant Eagle's SOM
10 system at its GERx facility?

11 MS. CARROLL: Objection. Form.
12 The witness may answer.

13 A. Again, the SOM system would be
14 under -- my understanding, it would be under
15 the security portion.

16 MR. LIVINGSTON: I'll pass the
17 witness and reserve any time I may still have
18 left.

19 MS. CARROLL: Is this a good time
20 to take a short break?

21 MR. LIVINGSTON: Sure.

22 THE VIDEOGRAPHER: We're off the
23 record.

24 (Recess had.)

25 THE VIDEOGRAPHER: We're on the

1 record.

2 EXAMINATION OF LEWIS COLOSIMO

3 BY MR. MOUGEY:

4 Q. Good morning, Mr. Colosimo, or good
5 afternoon. My name is Peter Mougey. I
6 represent the Plaintiffs in this case, sir.

7 I have a series of folders in front
8 of you. If you would please open the first one
9 that's marked 24, Tush 24, and we're going to
10 mark that for purposes today as number 1,
11 Exhibit 1.

12 - - - - -

13 (Thereupon, Plaintiffs' Deposition
14 Exhibit 1, Memorandum from Joseph
15 T. Rannazzisi to Special Agents in
16 Charge, Etc., dated October 27,
17 2009, with Attachments, Beginning
18 Bates Stamp US-DEA-00056902, was
19 marked for purposes of
20 identification.)

21 - - - - -

22 Q. And, if you would, sir, in the
23 bottom right-hand side are what we refer to as
24 Bates numbers. If you turn to 905 in your
25 document. All right. Sir, do you have that

1 open?

2 A. Yes.

3 Q. All right. And you and I should
4 have the same document up on the screen in front
5 of you. It's the interim policy for scheduled
6 investigations dated on the right-hand side
7 October 27, 2009, correct, sir?

8 A. Yes.

9 Q. And this is during the course of
10 your employment with the DEA? You were there
11 obviously in 2009, correct?

12 A. Yes.

13 Q. You can see under Attachments at the
14 bottom of this page the interim policy in lieu
15 of the diversion manual changes, sir. Do you
16 see that in the bottom under Attachments?

17 A. Yes.

18 Q. And, sir, this references the manual
19 that pertains to investigators such as yourself,
20 correct, sir?

21 A. Yes.

22 Q. And, sir, if you would please turn
23 to Bates number 05 under the section entitled
24 Due Diligence.

25 A. Okay.

1 Q. And, sir, let me just read these
2 first couple sentences to you. "Registrants
3 must have established effective controls against
4 diversion of controlled substances in accordance
5 with 21 USC 823. DEA will not approve, certify,
6 or assist registrants in conducting their due
7 diligence responsibilities, e.g. provide lists
8 or identify customers to whom they should or
9 should not sell."

10 Did I read that correctly, sir?

11 A. Yes.

12 Q. And, sir, is that consistent with
13 your understanding and your training with the
14 DEA that certain SOM policies, procedures,
15 including due diligence, were not sanctioned or
16 approved by the DEA?

17 A. That's my understanding, yes.

18 Q. And as this sentence goes on, it
19 says, "It is solely incumbent upon the
20 registrants to know their customers and the
21 potential abuses of the controlled substance
22 products for which they are approved."

23 Did I read that correctly, sir?

24 A. Yes.

25 Q. And, sir, is the fact that the

1 registrants, like HBC, that is solely incumbent
2 upon it to know its customers, is that
3 consistent with your training at the DEA?

4 A. Yes.

5 Q. Sir, if you would please open the
6 file that's marked P-GEN 3, which we're going to
7 mark as Exhibit 2.

8 - - - - -

9 (Thereupon, Plaintiffs' Deposition
10 Exhibit 2, Letter from Joseph T.
11 Rannazzisi to Dear Registrant,
12 dated June 12, 2012, with
13 Attachments, Beginning Bates Stamp
14 ABDCMDL00269683, was marked for
15 purposes of identification.)

16 - - - - -

17 Q. Sir, are you familiar with the fact
18 that the DEA sent registrants letters to help
19 educate them regarding the responsibilities
20 under the Controlled Substance Act?

21 A. My recollection is that DEA did
22 notify certain registrants of that.

23 Q. This is an example, I'll represent
24 to you, as one of the letters that was sent out
25 to the registrants. I would like to direct your

1 attention on this June 12, 2012 letter to the
2 last sentence of the third paragraph.

3 Now, sir, you're familiar with 21
4 CFR 1301.74(b), correct, sir?

5 A. Yes.

6 Q. And I think we were just referring
7 to that over the course of your testimony this
8 morning as the SOM policy, SOM requirement,
9 correct, sir?

10 A. Yes.

11 Q. And in this third paragraph the DEA
12 is reminding the registrants that they shall
13 design and operate a system to disclose to the
14 registrants suspicious orders of controlled
15 substances, correct?

16 A. Yes.

17 Q. And as the DEA is explaining to
18 registrants, like HBC, in the next sentence, the
19 regulation clearly places the responsibility on
20 the registrants to design and operate such a
21 system, correct, sir?

22 A. Yes.

23 Q. And in this last sentence of the
24 third paragraph, "Accordingly, DEA does not
25 approve or otherwise endorse any specific system

1 for reporting suspicious orders" -- is that last
2 sentence of the third paragraph that the DEA
3 does not approve or endorse consistent with your
4 training at the DEA?

5 A. Yes.

6 Q. And, sir, the fact that the DEA
7 didn't approve or endorse specific systems, that
8 was, in fact, communicated to registrants like
9 HBC, correct, sir?

10 A. That is my understanding, yes.

11 Q. I'm going to have you hold this
12 document because I'm going to come back to it.

13 I'd like to start with your first
14 report of investigation, which is in the folder
15 marked P-DEA-0052. We're going to mark this,
16 Mr. Colosimo, as Exhibit 3.

17 - - - - -

18 (Thereupon, Plaintiffs' Deposition
19 Exhibit 3, Report of Investigation
20 dated October 26, 2009, Beginning
21 Bates Stamp DEA-T1BCC-00001833, was
22 marked for purposes of
23 identification.)

24 - - - - -

25 Q. And this is a copy of the report of

1 investigation with your name on it dated
2 10-26-2009, correct, sir?

3 A. Yes.

4 Q. And this is one of the documents you
5 just went through with HBC's counsel, correct,
6 sir?

7 A. Yes.

8 Q. And, in fact, sir, you signed the
9 bottom of this report of investigation and dated
10 it November 4th, 2009, correct, sir?

11 A. Yes.

12 Q. And if you turn, Mr. Colosimo, to
13 the next page, Bates number 34, under
14 Recordkeeping, as part of your investigation,
15 you provided Mr. Carlson -- and he's an HBC
16 employee, correct, sir?

17 A. Yes.

18 Q. -- with a copy of 21 CFR part 1300
19 to the end, correct?

20 A. Yes.

21 Q. So in several of these reports of
22 investigation that you participated in, you
23 included the notation that you provided HBC a
24 copy of that reg, correct, all of the regs in
25 1300, correct?

1 A. Yes.

2 Q. Was that your practice, to provide
3 the registrants, like HBC, a copy of the
4 entirety of Regulation 1300 under the Controlled
5 Substance Act?

6 A. I don't know if that was my
7 practice with all pre-registrant
8 investigations. It would depend upon the
9 complexity of the business activity. I don't
10 know if I've approved other registrants, but
11 since distributors, a lot of the CFR pertains
12 to them, I thought it would be prudent to
13 provide the entire copy instead of printing
14 pages after -- page after page of the
15 regulations.

16 Q. And part of the copy that you
17 provided HBC included the reporting of
18 suspicious orders, correct, sir?

19 A. Yes.

20 Q. And, sir, it's -- was -- part of the
21 reason for including Chapter 1300 was to alert
22 or notify HBC that it was obligated to create
23 and design a system to identify orders of an
24 unusual size, frequency or pattern?

25 A. That's correct.

1 Q. Sir, if you would please open 46.
2 Mr. Colosimo, we're going to mark this as
3 Exhibit 4.

4 - - - - -

5 (Thereupon, Plaintiffs' Deposition
6 Exhibit 4, List of Citations Bates
7 Stamped DEA-T1BCC-00001825, was
8 marked for purposes of
9 identification.)

10 - - - - -

11 Q. Do you recognize this document, sir?

12 A. Yes.

13 Q. And, sir, this is -- the report that
14 we just left, Exhibit 3, included a reference to
15 a -- you providing a list of applicable
16 citations, correct?

17 A. Yes.

18 Q. And one of those citations is
19 Suspicious Orders, 1301.74(b), correct?

20 A. Yes.

21 Q. And another resource for HBC to use
22 to educate itself on its responsibility to
23 design and operate a system to identify
24 suspicious orders, you also included the DEA's
25 website specifically dedicated to diversion,

1 correct, sir?

2 A. Yes.

3 Q. And so what was the purpose of
4 providing registrants like HBC -- directing them
5 to the DEA's website?

6 A. My practice in doing that, in
7 preparing the -- that would be to give the
8 applicant all the available resources that I
9 have that I believe that they should have to --
10 to know what is required of them.

11 Q. So by including the DEA's website
12 with -- for registrants like HBC, there was a --
13 was there a significant amount of material on
14 that website related to registrants, like
15 distributors' obligations under the Controlled
16 Substance Act?

17 A. Yes.

18 Q. You would agree with me, sir, that
19 the DEA assists registrants, like the HBC,
20 understand the law and the regulations
21 associated with opiates under the Controlled
22 Substance Act, correct?

23 A. It's my -- as an employee of DEA, I
24 attempt to educate the applicant or the
25 registrant, and I point them to, as noted on

1 this, the DEA website, which has many different
2 forms of information, Q&As to letters to -- the
3 CFR -- I believe the CFR is even available on
4 that site.

5 Q. And in addition to the DEA's website
6 with information that's available to HBC and
7 other registrants, the DEA sends out advisory
8 letters with educational material, correct?

9 A. That's my understanding.

10 Q. And you understand as well that the
11 DEA conducted educational meetings around the
12 country to explain the registrant's duties and
13 obligations under the Controlled Substance Act,
14 correct?

15 A. That's my understanding, yes.

16 Q. And is it your understanding that on
17 the DEA's website that the DEA publishes the
18 results of its enforcement actions to help
19 educate registrants like HBC?

20 A. Excuse me. Did you say enforcement
21 actions?

22 Q. Yes, sir.

23 A. Yes, it would -- yes, that is on
24 the website, I believe.

25 Q. And all these are tools for the

1 registrant to design and operate a system to
2 identify suspicious orders that were of an
3 unusual size, frequency or patterns, correct,
4 sir?

5 A. I mean, that information is on
6 there, that information is available to the
7 registrant population. It's my understanding
8 that that information does give guidance and it
9 would be helpful.

10 Q. The very first exhibit we started
11 out with just a few minutes ago in Exhibit 1,
12 under the manual you were trained that it was
13 solely incumbent upon the registrant to know
14 their customers and the potential abuses of the
15 controlled substance products, correct?

16 A. Yes.

17 Q. And part of the material that's
18 published, whether it be through correspondence,
19 educational meetings conducted around the
20 country or the DEA's website, all of that
21 material provided by the DEA to registrants like
22 HBC was designed to help it fulfill its
23 obligations under the Controlled Substance Act,
24 correct?

25 A. That's my understanding. That's

1 what my experience is.

2 Q. Let's go through one of those
3 letters. We've marked it as Exhibit 3. We'll
4 put it up on the screen for you here.

5 You know who Mr. Rannazzisi is,
6 correct, sir?

7 A. Yes.

8 Q. And who do you understand, at this
9 point in June of 2012, Mr. Rannazzisi to be?
10 What was his role at the DEA?

11 A. I'm not certain of his exact title,
12 but he was essentially the head of DEA
13 diversion control. That's my understanding.

14 Q. If we can flip to the second page of
15 this document with his signature block, Joseph
16 Rannazzisi, Deputy Assistant Administrator,
17 Office of Diversion Control. Does that sound
18 about right?

19 A. Yes.

20 Q. And the first sentence of this
21 letter -- this letter is being sent to every
22 entity in the United States who is registered
23 with the Drug Enforcement Administration, DEA,
24 to manufacture or distribute controlled
25 substances. Did I read that right?

1 A. Yes.

2 Q. In 2012 HBC was registered with the
3 DEA as a distributor, correct?

4 A. Yes.

5 Q. And the DEA, in the second
6 paragraph, is informing registrants like HBC
7 that it was expressing its concerns regarding
8 drug abuse in the United States and highlighted
9 the responsibility of distributors to be
10 vigilant in the distribution of controlled
11 substances, correct, sir?

12 A. Yes.

13 Q. And through the course of the next
14 few sentences, do you see that Mr. Rannazzisi is
15 alerting registrants like HBC that it had sent
16 out prior letters, the example here in 2007, and
17 -- two of them in 2007, and 2006, that included
18 a list of factors that might indicate diversion;
19 correct, sir?

20 A. Yeah, that's what it indicates in
21 this letter.

22 Q. The next sentence, the last sentence
23 of the second paragraph, "The DEA encourages
24 registrants to take an integrated approach.
25 This point was emphasized in the December 2007

1 letter and DEA is once again bringing it to your
2 attention." Correct?

3 A. Yes.

4 Q. And the DEA is telling registrants
5 like HBC that the factors in the letters that
6 they had sent out in correspondence, two of them
7 in September '07 and one in September '06, that
8 these weren't comprehensive lists of all
9 possible indications of diversion, correct?

10 A. That's what it says, yes.

11 Q. And the last paragraph of this June
12 12, 2012 letter on the first page, "Registrants
13 who rely on rigid formulas to identify whether
14 an order is suspicious may fail to detect
15 suspicious orders." So this is all part of the
16 DEA's program to educate registrants so that
17 they can fulfill their obligations under the
18 Controlled Substance Act, correct, sir?

19 A. My understanding is this would be
20 part of that, yes.

21 Q. And the next few sentences in the
22 last paragraph on Bates number 83 gives several
23 reasons why rigid formulas may fail to detect
24 suspicious orders, correct?

25 A. Yes.

1 Q. If you turn to the next paragraph of
2 this same letter, Mr. Rannazzisi tells
3 registrants like HBC that the failure to
4 maintain effective controls against diversion is
5 inconsistent with the public interest as that
6 term is used in 21 USC Section 823 and 824,
7 correct, sir?

8 A. Yes.

9 Q. The next paragraph again points
10 registrants like HBC to the DEA's website that
11 has additional information, correct?

12 A. Yes.

13 Q. And the second to last paragraph
14 directing registrants like HBC to its website
15 even cites to a particular case from 2007
16 regarding the final order issued by the DEA
17 deputy administrator, correct? It's the
18 Southwood case.

19 A. Yes.

20 Q. In the closing paragraph of this
21 paragraph the DEA seeks to educate its
22 registrants on their responsibilities and
23 obligations under federal laws and regulations
24 to ensure that controlled substances are used
25 for legitimate purposes and to prevent

1 diversion, correct?

2 A. Yes.

3 Q. So similar to the packet that you
4 handed HBC with the entire Chapter 1300 and the
5 website, this one letter is another example of
6 the DEA educating registrants like HBC regarding
7 its obligations under the Controlled Substance
8 Act, correct?

9 A. I would agree with that.

10 Q. And the last sentence here, sir,
11 says your -- Mr. Rannazzisi is telling
12 registrants like HBC that its role in the proper
13 handling of controlled substances is critical
14 for public safety as it helps to protect society
15 against drug abuse and diversion. Did I read
16 that correctly, sir?

17 A. Yes.

18 Q. And the examples that we've just
19 reviewed in Exhibit 3 are consistent with the
20 messaging that went to registrants over a number
21 of years, correct, sir?

22 A. That's my understanding.

23 Q. If you would please open P-DEA 62,
24 which we're going to mark as Exhibit 5.

25 - - - - -

1 (Thereupon, Plaintiffs' Deposition
2 Exhibit 5, Letters from Joseph T.
3 Rannazzisi to Several Recipients,
4 Beginning Bates Stamp
5 US-DEA-00026067, was marked for
6 purposes of identification.)

7 - - - - -

8 Q. I'd like you, sir, to turn to Bates
9 number 83, several pages in. Do you see,
10 Mr. Colosimo, this is another piece of
11 correspondence to the Giant Eagle CEO? Do you
12 see that, sir?

13 A. Yes.

14 Q. And it's, again, signed by
15 Mr. Rannazzisi. Do you see that, sir?

16 A. Yes, it has his name on there.

17 Q. And, sir, this piece of
18 correspondence isn't dated, but do you see the
19 October 31, 2012 in the third paragraph?

20 A. Yes.

21 Q. Let's go back to the first sentence.
22 In October of '12 the DEA is alerting Giant
23 Eagle through its CEO that the diversion of
24 pharmaceutical controlled substances through the
25 United States is a growing national problem.

1 Do you see that, sir?

2 MS. CARROLL: Objection. Form.

3 Misstates the document.

4 The witness may answer.

5 A. That's -- the first sentence is as
6 you read it.

7 Q. Yes, sir.

8 And, sir, the DEA's education of
9 registrants like HBC to the fact that the
10 pharmaceutical controlled substances and
11 diversion of same, that that was a growing
12 national problem, is that consistent with your
13 understanding of the DEA's education of
14 registrants like HBC?

15 A. I would say that in my opinion that
16 sentence is consistent with my understanding.

17 Q. And the second sentence, "This
18 diversion stems from various sources," and
19 Mr. Rannazzisi lists pharmacy robberies and
20 thefts, pharmaceutical controlled substances,
21 but it also lists forged prescriptions, doctor
22 shoppers, or illegitimate prescriptions from
23 rogue practitioners; did I read that right, sir?

24 A. Yes.

25 Q. And, again, is this consistent with

1 your experience at the DEA, that Mr. Rannazzisi
2 is alerting registrants like HBC of different
3 avenues or possibilities of diversion?

4 MS. CARROLL: Objection.

5 A. I would agree that these are --
6 these are different forms of diversion that are
7 mentioned in that third sentence.

8 Q. And the second paragraph of this
9 letter from Mr. Rannazzisi is alerting the CEO
10 of Giant Eagle that the DEA is going to conduct
11 a meeting in Illinois to help with information
12 regarding identifying and responding to
13 potential diversion activity and to promote
14 compliance with the Controlled Substance Act,
15 correct, sir?

16 A. That's what it says.

17 Q. And, sir, is this consistent with
18 your understanding at the DEA that registrants
19 like HBC were invited to meetings with the DEA
20 to help educate them on potential areas of
21 diversion?

22 MR. LIVINGSTON: Objection.

23 A. It's my understanding that DEA was
24 holding meetings, seminars. I'm not -- I can't
25 recall this specific meeting that they're

1 referring to that -- in Illinois.

2 Q. But generally speaking, sir, you're
3 confident that the -- you understand that the
4 DEA was notifying registrants about conducting
5 meetings regarding their obligations under the
6 Controlled Substance Act and, more specifically,
7 diversion, correct, sir?

8 A. That's my understanding, yes.

9 Q. So the interactions between the DEA
10 and registrants like HBC regarding their
11 obligations to design and operate a system to
12 identify suspicious orders of unusual size,
13 frequency or patterns were not just during the
14 investigations or audits that you performed, but
15 a wide number of opportunities for HBC to
16 educate itself regarding its responsibilities?

17 MR. LIVINGSTON: Objection.

18 A. This letter is an example of an
19 opportunity for the registrant to be educated.

20 Q. I'm sorry. That was probably my
21 best question of the day and I just read it into
22 the mute. Let me read that again.

23 Mr. Colosimo, it's consistent with
24 your understanding that HBC's opportunities to
25 educate itself on its obligations under the

1 Controlled Substance Act extended beyond the
2 interactions with you and other investigators
3 during audits, correct?

4 A. I believe so, yes.

5 Q. Sir, if you would, please, open the
6 file I have marked as P-DEA 65. I'm going to
7 mark this as Exhibit 6.

8 - - - - -

9 (Thereupon, Plaintiff's Deposition
10 Exhibit 6, Report of Investigation
11 dated August 13, 2013, Beginning
12 Bates Stamp US-DEA-00030485, was
13 marked for purposes of
14 identification.)

15 - - - - -

16 Q. And I apologize for not following
17 along. Sir, was this -- did you take part with
18 this report of investigation?

19 A. You said this is under -- I'm
20 sorry -- DEA 65?

21 Q. Yes.

22 A. No, I was not -- I was not part of
23 this investigation.

24 Q. Was it your practice, sir -- you
25 were part of investigations after this August

1 13, 2013 report, correct?

2 A. I was a part of the pre-registrant
3 investigation for this facility and I was part
4 of the on-site pre-registrant investigation of
5 the -- Giant Eagle's facility in Freedom,
6 Pennsylvania. I was not part of the scheduled
7 or cyclic investigation of either warehouse or
8 facility that distributed controlled
9 substances.

10 Q. When conducting a -- I'm going to
11 call it a post-investigation or to go back and
12 look at or review prior reports of
13 investigation?

14 A. That would be part of my
15 experience, my procedures when I do my
16 investigation.

17 Q. Do you recall reviewing -- let's put
18 it up on the screen here -- the August 13, 2013
19 report of investigation? And, sir, if you could
20 turn to Bates number 97 under the Due Diligence
21 section.

22 A. Yes.

23 Q. Sir, you see I have it marked here
24 in the middle of the page that HBC was alerted
25 that it did not have a computerized software

1 system to identify suspicious orders?

2 A. I don't know that the report says
3 they were alerted, but the representative
4 advised that they had no computerized software
5 system and they informed the DEA investigators
6 on-site of that fact.

7 Q. And, sir, do you have an
8 understanding who Rogos is, R-o-g-o-s?

9 A. Earlier in that section he's
10 identified as the operations manager for
11 HBC/Giant Eagle.

12 Q. And in the section at the bottom of
13 Bates number 97, Rogos advised that if a Giant
14 Eagle pharmacy were to receive unusually high
15 orders of controlled substances from HBC
16 deviating from other stores, he relayed that it
17 would be noticed at the Giant Eagle, Inc.
18 headquarters, right, sir?

19 A. Yes.

20 Q. And he advised the DEA on the next
21 page, Bates number 98 -- I apologize. It's on
22 Bates number 97 -- he would bring the issue to
23 the attention of Greg Carlson and Kim Remas at
24 Giant Eagle's headquarters. Do you see that at
25 the bottom, sir?

1 A. Yes.

2 Q. On the next page, Bates number 98,
3 Investigator Conlon advised Rogos to develop a
4 better system of due diligence.

5 Do you see that, sir?

6 MS. CARROLL: Excuse me, counsel.
7 We're not getting a good focus on this.

8 Much better. Thank you.

9 A. Yeah, the report indicates that
10 Rogos was advised to develop a better system of
11 due diligence.

12 Q. Sir, if you would please open the
13 file that's labeled P-DEA 69.

14 - - - - -

15 (Thereupon, Plaintiffs' Deposition
16 Exhibit 7, Report of Investigation
17 dated December 3, 2014, Beginning
18 Bates Stamp US-DEA-00030618, was
19 marked for purposes of
20 identification.)

21 - - - - -

22 Q. This is a copy of another DEA report
23 of investigation dated 12-3-2014 that was part
24 of its file, correct, sir?

25 A. Yes.

1 Q. And it's dated 12-3-2014, correct,
2 sir?

3 A. Yes.

4 Q. And on Bates number 30 of this
5 document there's another section similar to the
6 last report of investigation titled Due
7 Diligence, correct, sir?

8 A. Yes.

9 Q. Wherein HBC advised the DEA that its
10 parent company has no computerized software
11 system to indicate that an order may be
12 suspicious, correct, sir?

13 A. Yes.

14 Q. And HBC, through Mr. Rogos, advised
15 that if a Giant Eagle pharmacy were to receive
16 unusually high orders of controlled substances
17 from HBC, deviating from other stores, it would
18 be noticed at the Giant Eagle, Inc. headquarter
19 level, correct, sir?

20 A. Yes, that's what it says there.

21 Q. And, sir, I think that's the second
22 entry that we've seen in the DEA's report of
23 investigation that headquarters was monitoring
24 orders from HBC's pharmacies, correct?

25 A. That was cited in here as well as

1 the prior investigation that you mentioned.

2 Q. So you would expect at this point in
3 time, based on Mr. Rogos' representation to the
4 DEA, that HBC or Giant Eagle would have a --
5 would have designed a system to identify
6 suspicious orders at headquarters, correct, sir?

7 MR. LIVINGSTON: Object to the
8 form.

9 A. This is the second report that
10 indicates that there's no computerized software
11 system and that Giant Eagle assured the
12 investigators that they would be notifying
13 Giant Eagle headquarters of that fact.

14 Q. And Mr. Rogos again relays at the
15 bottom of this report, consistent with the last
16 report that we looked at, that he will bring
17 this issue to the -- if you turn the page to
18 Bates number 81 -- attention of Greg Carlson and
19 Kim Remas at Giant Eagle's headquarters
20 controlled substance purchasing unit, correct?

21 A. That's what it says, yes.

22 Q. Mr. Colosimo, if you would please
23 open the file marked DEA 53, which we're going
24 to mark as Exhibit 8.

25 - - - - -

1 (Thereupon, Plaintiffs' Deposition
2 Exhibit 8, Report of Investigation
3 dated January 11, 2016, Beginning
4 Bates Stamp DEA-T1BCC-00001846, was
5 marked for purposes of
6 identification.)

7 - - - - -

8 Q. This is dated 1-11-2016 and this was
9 a report of investigation conducted by you,
10 correct, sir?

11 A. Yes.

12 Q. And you also signed this report on
13 1-11-2016, correct, sir?

14 A. Yes.

15 Q. And, sir, you made a notation in
16 this report, Bates number 48, that HBC or Giant
17 Eagle, that it now had written policies and
18 standard operating procedures regarding its
19 obligations under the Controlled Substance Act
20 to identify suspicious orders, correct, sir?

21 A. Yes.

22 Q. Now, sir, let me -- so the jury has
23 a little bit of context, Giant Eagle has more
24 than 200 pharmacies that were serviced through
25 this distribution center, correct?

1 A. That's what I recall.

2 Q. And do you recall, sir, that -- I
3 think during your testimony earlier today --
4 that this one distribution center serviced all
5 200 plus pharmacies?

6 A. I mean, that's what my
7 understanding was and is, that I don't know if
8 Giant Eagle had multiple distributors at the
9 time or since our office approved the
10 facilities, but my understanding was that this
11 facility was distributing to multiple states
12 that had Giant Eagle pharmacies.

13 Q. And that Giant Eagle had relayed to
14 either you and/or your colleagues in those prior
15 reports of investigation that headquarters was
16 keeping an eye or would pick up on orders that
17 were of unusual sizes or frequency or pattern,
18 correct?

19 MS. CARROLL: Objection. Form.
20 The witness may answer.

21 A. Yeah. My recollection is that I
22 was informed that -- by Giant Eagle personnel
23 that headquarters was monitoring customer
24 pharmacy orders.

25 Q. Sir, would it surprise you in years

1 like 2010, '11, '12, '13, '14 that this -- the
2 HBC pharmacies were dispensing more than 20
3 million dosage units of oxycodone and
4 hydrocodone a year?

5 MR. LIVINGSTON: Objection to form.

6 MS. CARROLL: Excuse me, counsel.
7 I'm going to object to the scope. I think
8 we're getting away from distribution facility
9 inspections and we're talking about pharmacies.
10 Would you care to rephrase?

11 MR. MOUGEY: No, I don't.

12 Q. Mr. Colosimo, would it surprise you
13 that HBC was dispensing more than 20 million
14 dosage units a year in '11, '12, '13, '14 of
15 oxycodone and hydrocodone?

16 MR. LIVINGSTON: Objection again.
17 It's also beyond the Touhy scope.

18 MS. CARROLL: I'll reiterate my
19 objection and direct the witness not to answer.

20 MR. MOUGEY: I'm sorry. You're
21 going to direct the witness not to answer?

22 MS. CARROLL: If the question is
23 about dispensing from pharmacies -- is that the
24 question?

25 MR. MOUGEY: Ms. Carroll, maybe you

1 missed it, but in response to the -- HBC's and
2 Giant Eagle's responsibilities under the
3 Controlled Substance Act, the last two reports
4 of investigation have referenced the DEA to
5 HBC's corporate monitoring of orders from its
6 pharmacies. My suggestion is to let him answer
7 and we can -- after reading the record, if you
8 want to object to it later, I think you've
9 preserved it.

10 MR. LIVINGSTON: I was not
11 permitted to ask those kinds of questions
12 because of the limitations imposed by the Touhy
13 letter.

14 MR. MOUGEY: HBC is the party that
15 directed the DEA to its corporate monitoring of
16 orders from its pharmacies and I'm simply
17 asking a follow-up question that's in the
18 report.

19 MR. LIVINGSTON: No. You're asking
20 a different question about dispensing.

21 MR. MOUGEY: Well, the only orders
22 that the pharmacies put in were in relation to
23 its own dispensing, correct, Mr. Colosimo?

24 MS. CARROLL: The Touhy authorizes
25 Mr. Colosimo to speak to his investigations of

1 Giant Eagle distribution facilities. To the
2 extent that you're discussing a report as to
3 those investigations, I think it's within the
4 scope. Beyond that, activities at pharmacies,
5 et cetera, I believe it's beyond the scope.

6 MR. MOUGEY: I'm not asking about
7 activities at pharmacies. I'm just simply
8 asking if --

9 Q. Let's do it this way. Do you have a
10 feel, Mr. Colosimo, or an understanding of how
11 many dosage units HBC was running through its
12 distribution center?

13 MR. LIVINGSTON: Objection.

14 A. I can't recall those amounts for
15 those particular drugs.

16 Q. Would it surprise you, sir, that the
17 numbers were in the tens of millions on an
18 annual basis that were coming through HBC or
19 Giant Eagle's distribution center of just
20 oxycodone and hydrocodone?

21 MR. LIVINGSTON: Objection to form.

22 A. Again, I don't know what the amount
23 was or -- and I can't recall what would be an
24 acceptable or an excessive amount.

25 Q. Yes, sir, I understand that. For

1 context, what I'm looking for is volume, and I'm
2 going to represent to you, sir, that there were
3 tens of millions of dosage units of oxycodone
4 and hydrocodone coming through HBC or Giant
5 Eagle's distribution center. Okay, sir? During
6 the scope of your investigative reports, you and
7 your colleagues at the DEA were not reviewing
8 order by order from HBC or Giant Eagle
9 pharmacies, correct, sir?

10 A. I'm sorry. What do you mean,
11 "order by order"?

12 Q. From orders from the pharmacies
13 to -- HBC/Giant Eagle pharmacies to -- for oxy
14 and hydro. You were not reviewing those orders
15 one by one, correct, sir?

16 A. One by one, we did not do that, I
17 did not do that.

18 Q. Yes, sir. And part of your
19 investigations -- you weren't reviewing these
20 millions of pills and the orders during your
21 investigations, correct, sir?

22 A. My investigation was the
23 pre-registrant investigation of HBC, then later
24 the Giant Eagle facility.

25 Q. In the course of those

1 investigations or your reviews, it was not the
2 DEA's practice to review order by order,
3 correct, sir?

4 A. It was -- that was not my practice,
5 and I don't -- I can't speak to the other
6 investigators, but my experience is that we
7 would not have been reviewing order by order.

8 Q. And, sir, it would almost be --
9 based on your practice and experience, it would
10 be impossible to review the hundreds of
11 thousands or millions of orders that came in
12 through HBC's pharmacies during the scope of
13 your investigation, correct?

14 MS. CARROLL: Object to the form.
15 The witness may answer if he feels
16 it's within the scope of the authorization.

17 A. You had mentioned or asked a few
18 times order by order. That's not something
19 that -- that I would have been doing for my
20 investigations, order by order.

21 Q. Or that you observed any other DEA
22 investigators reviewing orders, correct, sir?

23 MR. LIVINGSTON: Object to the
24 form.

25 A. Correct. I did not observe other

1 investigators reviewing order by order.

2 Q. Sir, did it remain consistent with
3 your practice at the DEA on this Exhibit 8 2016
4 investigation that the DEA was not reviewing and
5 approving HBC or Giant Eagle's SOM policy or
6 system that was in place when you approved their
7 application or its application in 2016, correct?

8 MR. LIVINGSTON: Object to the
9 form.

10 MS. CARROLL: I'm sorry, counsel.
11 Could you repeat the question?

12 MR. MOUGEY: I think that was a bad
13 question. Let me restate it. I apologize.

14 Q. Sir, did it remain consistent with
15 your practice at the DEA and Exhibit 8, this
16 report of investigation, that the DEA was not
17 approving HBC/Giant Eagle's SOM policies and/or
18 systems that were in place, correct?

19 MR. LIVINGSTON: Object to the
20 form.

21 A. We reviewed the policy to the
22 extent that it was summarized in the
23 description of what they were doing, but we did
24 not sanction -- me personally and my
25 supervisor, Mr. Dittmer, did not sanction or

1 approve of that suspicious order system in
2 place.

3 MR. MOUGEY: I don't think I have
4 any more questions. If you guys give me less
5 than a five-minute break, I'll confirm with my
6 colleagues and I don't think I have anything
7 else. If you could give me just a few minutes
8 off the record.

9 THE VIDEOGRAPHER: We're off the
10 record.

11 (Recess had.)

12 MR. MOUGEY: On behalf of
13 Plaintiffs, we don't have any further
14 questions.

15 FURTHER EXAMINATION OF LEWIS COLOSIMO
16 BY MR. LIVINGSTON:

17 Q. Can you look at our Exhibit, which
18 is the binder, 3, at page 70? So this is the
19 report of investigation of the HBC facility from
20 December of 2014. You were just asked some
21 questions about this exhibit, which was
22 Plaintiffs' Exhibit 7, by Mr. Mougey. Do you
23 see under 10, Meeting with Management, it says,
24 "During this meeting the investigators advised
25 Giant Eagle's management that both recordkeeping

1 and security are in full compliance with the
2 requirements in Title 21 CFR"? That tells you,
3 sir, that Giant Eagle was told at this time that
4 it was meeting all of the security requirements,
5 including the SOM regulation, correct?

6 MS. CARROLL: Object to the form.

7 The witness may answer.

8 A. Yeah. According to that sentence,
9 it does indicate that Investigators Conlon and
10 Sousa advised Rogos and Kuchta that
11 recordkeeping and security are in full
12 compliance. That's what it says.

13 Q. Okay. And, sir, if you go back to
14 the previous page -- I guess it's actually page
15 69 of this exhibit -- this is that discussion
16 that -- between Mr. Rogos and the DEA
17 investigators about Giant Eagle's SOM system at
18 the time, correct? You were just asked some
19 questions about this from Mr. Mougey.

20 A. Yes.

21 MS. CARROLL: Objection. Form.

22 The witness may answer.

23 Q. Sir, isn't this literally word for
24 word identical to what was in the previous
25 report from August of 2013 that we looked at

1 earlier?

2 A. My understanding is that this is
3 very similar. I don't know how word for word
4 it would be, I would have to look at it closer,
5 but it's similar to what was addressed in the
6 prior investigation.

7 Q. And don't you find it odd that
8 there's no reference to the prior discussion in
9 this section of the report? Wouldn't that be
10 normal if in 2013 there had been a discussion
11 where the DEA had made a recommendation to Giant
12 Eagle and that the same discussion would be
13 reproduced without any reference back to the old
14 discussion?

15 MS. CARROLL: Object to the form.
16 The witness may answer.

17 A. I didn't author this.

18 Q. No. I'm just saying if you were
19 drafting this report, wouldn't you reference the
20 prior discussion?

21 MS. CARROLL: Object to the form.
22 The witness may answer.

23 A. If I'm to testify, speak about my
24 own experience, my own practices, I would -- I
25 would make reference that this was -- it was

1 brought up to the Giant Eagle personnel in the
2 prior visit.

3 Q. So isn't it possible that this is
4 just, you know, a cut and pasting of the prior
5 report, of this section from the prior report?

6 MS. CARROLL: Object to the form.
7 The witness may answer.

8 A. That's -- that would be speculation
9 on my part.

10 Q. Right. Just that it's a
11 possibility?

12 A. Is it possible? Is it not
13 possible? It's possible, but I don't know what
14 was done on this. I'm just reading this at --
15 as it states, what was said, what was
16 discussed.

17 Q. And earlier today I asked you some
18 questions about some internal Giant Eagle
19 documents referring to a threshold system that
20 was in place after the 2013 inspection. Do you
21 remember I asked you some questions about that?

22 A. I recall threshold came up, but I
23 can't recall specifically the context that
24 you --

25 Q. Remember, one of the e-mails

1 referred to reporting the flagged order to you
2 and you just didn't recall whether you were
3 notified or not? Do you remember that?

4 A. Yes.

5 Q. And so what you don't know, sir, is
6 whether or not Giant Eagle, in fact, in response
7 to the recommendation from the DEA as to how to
8 improve its SOM system, whether or not it, in
9 fact, went with an automated system by the end
10 of 2013? You have no knowledge of that sitting
11 here today; is that correct?

12 MS. CARROLL: Object to the form.
13 The witness may answer.

14 A. Yeah, I don't know for certain
15 whether they had that system in place as of
16 that date.

17 Q. Would you agree that based on your
18 interactions with Giant Eagle, you understood
19 Giant Eagle to always be trying to improve its
20 security systems, including its SOM system?

21 A. I don't know what -- I don't know
22 that I can answer that question. I don't know
23 what deliberations Giant Eagle employees had,
24 whether they were doing all that they could do
25 to ensure their system was -- was sufficient,

1 was effective.

2 Q. Let me rephrase it and maybe you'll
3 be more comfortable answering this one. Would
4 it be fair to say that as Giant Eagle's SOM
5 system was described by Giant Eagle to you over
6 the years, that Giant Eagle's SOM system
7 improved as described?

8 A. In reviewing this from the 2009
9 pre-registrant inspection through the
10 inspections that were done at HBC to my
11 pre-registrant investigation in '15, '16, that
12 are -- that system was -- it was better
13 described, it seemed -- it was a formal system.
14 In effect, I don't know if it was more
15 effective than an earlier system, but it was
16 definitely -- it was -- by the time of the
17 pre-registrant investigation in '15 and '16,
18 there was a -- it appeared to be a more
19 formalized detailed monitoring system in place.

20 - - - - -

21 (Thereupon, Defendants' Deposition
22 Exhibit 10, E-Mail from Victor
23 Vercammen to Lewis Colosimo and
24 Nancy Jackson dated June 3, 2019,
25 was marked for purposes of

1 identification.)

2 - - - - -

3 Q. Look at Exhibit 10, page 1, in our
4 binder. Do you see this is an e-mail from
5 Victor Vercammen dated June 3, 2019 to yourself
6 and Nancy Jackson. Is she a colleague of yours
7 at the DEA?

8 A. Yes. At the time she was my
9 supervisor.

10 Q. Do you recall meeting with
11 Mr. Vercammen around this time?

12 A. I recall somewhere around that
13 time. It was not a meeting. It was a
14 conference call.

15 Q. It refers to a -- I guess a
16 conference call you had on May 15th of 2019 to
17 discuss recent changes in Ohio law related to
18 suspicious order reporting by distributors and
19 the potential impact of those changes on federal
20 suspicious order reporting. Do you recall that
21 being the subject of your discussion with
22 Mr. Vercammen?

23 A. This is -- this is the e-mail that
24 summarizes that. Part of what we did discuss
25 was whether DEA's or the CFR cite or DEA

1 reporting requirements had changed based upon
2 the change in Ohio, Ohio -- the State of Ohio's
3 reporting requirements.

4 Q. Right. And was it your
5 understanding that essentially Ohio law was
6 requiring every potentially -- potential
7 suspicious order that was flagged by a SOM
8 system to be reported and Giant Eagle was
9 wondering whether the DEA wanted to receive a
10 report of everything that's flagged for just
11 those after investigation that were determined
12 to be, in fact, suspicious orders?

13 MS. CARROLL: Object to the form.
14 The witness may answer.

15 A. Yeah. Could you repeat that again?

16 Q. Why don't we just go through the
17 letter. Maybe it will be easier.

18 The next paragraph says, "As we
19 described our current system, Giant Eagle has a
20 multi-layered system of controls to prevent
21 theft and diversion which also prevents and
22 detects suspicious orders if they ever occur."
23 And then again it says, "Corporate, warehouse
24 and pharmacy control." So was it your
25 understanding that Giant Eagle explained to you

1 at this point in time that their suspicious
2 order monitoring system had controls at all
3 three levels of the company?

4 A. I don't recall the specifics,
5 whether those three items, corporate, warehouse
6 and pharmacy, were -- if those were discussed,
7 if they were discussed in any detail. I don't
8 recall specifically those three, but I just --
9 I recall a general discussion of whether that
10 CFR cite or DEA's requirement had changed with
11 a change in Ohio reporting requirements.

12 Q. If we go down a little further, it
13 says, "GERx is closely monitored by Giant Eagle
14 corporate headquarters, including controls over
15 controlled substance inventories."

16 Is that your understanding that --
17 how Giant Eagle's controls -- I mean,
18 suspicious order monitoring system works, that
19 there's corporate oversight of controlled
20 substance inventories?

21 MS. CARROLL: Object to the form.

22 Witness may answer.

23 A. I mean, it's my understanding that
24 Giant Eagle headquarters corporate office would
25 monitor those items closely. I don't know how

1 close it is. This is what the e-mail says.

2 But my understanding is that there is
3 monitoring that they do.

4 Q. All right. Then it goes on to say
5 that there are controls at the warehouse level
6 and also at the pharmacy level. Is that your
7 understanding today, that Giant Eagle suspicious
8 order monitoring system has controls at all
9 three levels?

10 A. I don't recall that these specific
11 items were discussed, if this is statements of
12 what Giant Eagle is doing or -- I don't recall
13 specifically the detail that he, you know,
14 lists in this e-mail.

15 Q. Well, whether you discuss it or not,
16 it's set forth in this letter, and so did this
17 letter educate you then that Giant Eagle now has
18 controls at all three levels?

19 MS. CARROLL: Objection. Form.
20 The witness may answer.

21 A. I mean, that's what is represented
22 in this -- this e-mail.

23 Q. Skip down to the next paragraph. It
24 says, "An additional corporate level control is
25 a software program that monitors all pharmacy

1 orders placed with GERx based upon past ordering
2 trends and other information in order to detect
3 orders of interest."

4 Do you see that?

5 A. Yes.

6 Q. So you would agree that this is sort
7 of a form of an automated suspicious order
8 monitoring system, correct, as described?

9 MS. CARROLL: Object to the form.

10 The witness may answer.

11 A. As described there, that appears to
12 be a computerized software program.

13 Q. And then it says, "When orders of
14 interest are identified by this program, Giant
15 Eagle investigates and documents the reasons for
16 the orders. In nearly all cases the orders of
17 interest are resolved as human error, including
18 accidental, duplicate or large orders, episodic
19 increases in legitimate prescriptions presented
20 to the pharmacies or similar reasons," and he
21 calls them i.e. cleared orders. "As we
22 discussed, Giant Eagle has not been reporting
23 the cleared orders to DEA, Ohio, Pennsylvania or
24 any other authority since there is no known risk
25 of diversion. However, due to the recent

1 changes in Ohio law, we understand that the
2 cleared orders must now be reported to Ohio and
3 we considered whether DEA and other authorities
4 similarly want us to report all cleared orders
5 in addition to actually suspicious orders."

6 So does that refresh your
7 recollection that Giant Eagle was asking the
8 DEA whether it wanted all orders of interest to
9 be -- to be notified of all orders of interest
10 or just orders that are determined to be
11 suspicious after investigation?

12 MS. CARROLL: Object to the form.
13 The witness may answer.

14 A. It was -- specifically we did not
15 delve into the Ohio requirements. We
16 emphasized -- I'm speaking we, myself and the
17 group supervisor, Nancy Jackson, that the CFR
18 regulation did not change, that they were --
19 this has not changed their obligation since the
20 inception of that CFR order, that they were
21 required to design and operate that system and
22 to report suspicious orders. We directed
23 Mr. Vercammen as well as Mr. Chunderlik to
24 consult with the Ohio board for clarification
25 with what they required. We indicated there's

1 no change in what DEA -- DEA required.

2 Q. But if you go to the next paragraph,
3 it says, "It was further suggested that DEA does
4 not want to receive reports regarding cleared
5 orders and instead Giant Eagle should only
6 report those orders that have not been cleared
7 and not filled because it deems them
8 suspicious."

9 Is that, in fact, the directive
10 that you and Ms. Jackson gave Giant Eagle at
11 the time?

12 A. I don't -- I don't recall the
13 discussion of cleared orders. Orders came up.
14 I can't recall specifically, but we told them
15 that you are to report to DEA what you deem to
16 be a suspicious order. That did not change
17 from -- regardless of any change in Ohio state
18 law.

19 Q. And by suspicious order, you mean an
20 order that, after investigation, has been
21 determined to be suspicious, correct?

22 A. What's your question again?

23 Q. When you say "suspicious order,"
24 you're referring to an order that, after
25 investigation, has been determined to, in fact,

1 be a suspicious order?

2 A. They did not -- my understanding is
3 that they did not use the word "suspicious
4 order." Suspicious order was only what they
5 deemed to be suspicious. We did not delve into
6 the criteria that they -- they explained to us
7 some of the things -- some of the steps that
8 they would do, but our view was that you report
9 to us suspicious order and that that did not
10 change with the change in Ohio law.

11 Q. The last paragraph says, "In
12 summary, we agreed that Giant Eagle will
13 continue to report to DEA only those orders that
14 have not been cleared and where such order was
15 refused due to our determination that the order
16 is actually suspicious, and will not,"
17 underscore, "report cleared orders that are
18 being reported to Ohio under the new law."

19 Is that what the agreement was? Is
20 that accurate?

21 A. We explained to them that whatever
22 you were doing before the Ohio law changed, you
23 were to continue to do that with regard to
24 reporting to us suspicious orders.

25 Q. At the very end Mr. Vercammen says,

1 "If I have misunderstood any of our discussions,
2 please let me know as soon as possible."

3 Did you ever respond to his e-mail?

4 A. That e-mail -- actually, I don't
5 know if that -- that e-mail was directed to
6 Supervisor Jackson. They may have had an -- if
7 I could look at the top of that. That's not
8 how I spell my first name.

9 Q. So you don't think -- did you
10 receive this?

11 A. I don't know if it was sent to me
12 directly. I did -- I did review this. I don't
13 know -- I don't recall responding to it. I
14 don't know if Supervisor Jackson responded to
15 that.

16 Q. I think you testified a few minutes
17 ago about how the DEA's view is that
18 distributors like Giant Eagle should be vigilant
19 with respect to trying to prevent diversion in
20 complying with the DEA's regulations, correct?

21 A. That they should be vigilant?

22 Q. Yes.

23 A. Yes.

24 Q. And, sir, based on all your
25 interactions with Giant Eagle, you saw no

1 evidence that Giant Eagle was acting in any way
2 other than vigilant with respect to complying
3 with the DEA's regulations?

4 A. I don't know all that they've done
5 to comply with DEA regulations.

6 Q. That's why I'm limiting my question
7 to your interactions.

8 A. And that's a broad -- my
9 interaction with Giant Eagle is -- has been
10 under many different formats or scenarios, from
11 pharmacy inspections to pre-inspections,
12 security suggestions. Which in particular are
13 you referring to?

14 Q. I'm not aware of all your
15 interactions. I just know you've had many, and
16 that's why I'm asking the question the way I am.

17 Are you aware of any -- is there
18 any evidence that you can point to us that
19 suggests that Giant Eagle was anything other
20 than vigilant with respect to complying with
21 the DEA's regulations?

22 A. I don't have direct information
23 that they were not compliant.

24 Q. To your knowledge, there was never
25 an administrative action of any kind taken

1 against Giant Eagle's distribution facilities
2 for not complying with the DEA's regulation?

3 A. My recollection is there was not
4 administrative action taken.

5 Q. We talked a little bit about SOM
6 systems, automated versus sort of a manual
7 system. From the DEA's perspective, the DEA
8 doesn't care whether it's automated or manual,
9 right?

10 A. DEA, from my perspective, that is
11 not dictated. In that specific CFR cite it
12 does not indicate whether it's automated or
13 computer -- or manual. Sorry.

14 Q. Why don't you go to Exhibit 15.

15 - - - - -

16 (Thereupon, Defendants' Deposition
17 Exhibit 15, Thomas Prevoznik
18 Deposition Excerpt, was marked for
19 purposes of identification.)

20 - - - - -

21 Q. This is testimony that Thomas
22 Prevoznik gave -- He's from DEA headquarters --
23 earlier in this litigation. Do you know him?

24 A. I do know Mr. Prevoznik, yes.

25 Q. If you go to page 5 of this exhibit,

1 on page 180 of the transcript, line 12, he was
2 asked, "Does it matter to the DEA whether a
3 registrant reviews orders manually or uses an
4 automated system?" And his answer was: "No, it
5 doesn't matter."

6 Do you agree with his testimony?

7 MR. MOUGEY: Objection.

8 A. I don't know that I could say that
9 it does not matter. I don't know if I would
10 necessarily agree with that or disagree, but it
11 would depend on the distributor. It would
12 depend on several factors, I believe. I
13 can't -- I wouldn't agree that it's a blanket
14 statement that it does not matter.

15 Q. Well, with respect to Giant Eagle,
16 the DEA found that its SOM system, both when it
17 was described as a manual system and when it was
18 later described as an automated system, were
19 both in compliance with the DEA's security
20 regulations, correct?

21 MS. CARROLL: Object to the form.

22 The witness may answer.

23 A. I didn't -- did not go beyond the
24 scope of the CFR cite that -- the system -- the
25 registrant has to design and operate that

1 system. I don't know how effective Giant
2 Eagle's system was.

3 Q. Well, we know there were subsequent
4 cyclic investigations of Giant Eagle's HBC
5 facility, we just went over those investigation
6 reports, where the SOM system that Giant Eagle
7 had was specifically discussed with the DEA and
8 a recommendation was made to improve the system
9 but a finding was made that the system was in
10 full compliance, correct?

11 MR. MOUGEY: Objection.

12 MS. CARROLL: Object to the form.
13 The witness may answer.

14 A. Yes. Based upon the statements in
15 those reports that -- the investigators did
16 indicate that recordkeeping and security were
17 in compliance.

18 MS. CARROLL: Excuse me. Could we
19 get a time check real quick?

20 THE VIDEOGRAPHER: Sure. One
21 moment. We went on the record at 2:15 this
22 last segment. It's now 2:42.

23 MR. LIVINGSTON: I have a total of
24 three and a half hours, so how much time have I
25 used?

1 THE VIDEOGRAPHER: Three hours and
2 one minute during your first segment, and
3 you're just about 30 more minutes -- about 28
4 minutes.

5 MR. LIVINGSTON: Well, I'm done. I
6 have no more questions. Thank you,
7 Mr. Colosimo.

8 THE WITNESS: You're welcome.

9 FURTHER EXAMINATION OF LEWIS COLOSIMO
10 BY MR. MOUGEY:

11 Q. Mr. Colosimo, I have just a couple
12 of quick questions. Bear with me here.

13 I'm going to go back to what we
14 marked as Exhibit 2, a June 12, 2012 letter
15 from the DEA to registrants, including HBC and
16 Giant Eagle. Mr. Colosimo, you would agree
17 that under no state, form or fashion did the
18 DEA approve or otherwise endorse any specific
19 system for reporting suspicious orders,
20 correct, sir?

21 MR. LIVINGSTON: Object to the
22 form.

23 A. That is what is indicated in the
24 letter from Rannazzisi and, from my experience,
25 I did not approve or endorse the suspicious

1 order system.

2 Q. And that is also consistent with
3 your training at the DEA, that investigators did
4 not approve suspicious order systems, correct,
5 sir?

6 A. Yes.

7 MR. MOUGEY: No further questions.

8 FURTHER EXAMINATION OF LEWIS COLOSIMO

9 BY MR. LIVINGSTON:

10 Q. I just have a couple follow-ups. I
11 want to make sure I understand this.

12 If you're looking at a vault for a
13 distributor to make sure it complies with the
14 security requirements, you don't approve the
15 vault, what you decide is whether the vault
16 meets the security requirements for a vault,
17 correct? That's what you do?

18 MS. CARROLL: Object to the form.

19 The witness may answer.

20 A. You look at the vault and you
21 compare it with the specific CFR criteria to
22 ensure that it does comply. There's specific
23 criteria that are outlined in the CFR.

24 Q. Right. The DEA doesn't have one
25 company -- one manufacturer of vaults and one

1 type of vault that everybody has to use that has
2 the DEA stamp of approval, you just go
3 through -- you look at the vault, you make sure
4 that it complies with the requirements under the
5 security regulations, correct?

6 A. I would say that's a fair way to
7 characterize that.

8 Q. And the same thing is true with
9 respect to the SOM system; there's no particular
10 SOM system that the DEA has approved that has
11 the DEA stamp of approval, that's up to the --
12 to each individual registrant to come up with
13 their own system; what you do is you make sure
14 that that system as described to you meets the
15 requirements for a SOM system?

16 MR. MOUGEY: Objection.

17 Q. In other words, it complies with the
18 SOM system regulation?

19 MR. MOUGEY: Objection.

20 MS. CARROLL: Objection to form.
21 The witness may answer.

22 A. What I do is to ensure that they
23 have a system. I don't go beyond what is in
24 that CFR cite, that it has to be -- they have
25 to design and operate the system to report

1 suspicious orders, and it gives those three
2 types of suspicious orders. So whatever system
3 they have in place, it needs to do that, it
4 needs to detect those and report to DEA the
5 suspicious order.

6 MR. LIVINGSTON: Thank you. I have
7 no more questions at this time.

8 MR. MOUGEY: Plaintiffs don't have
9 any further questions.

10 THE VIDEOGRAPHER: We're off the
11 record.

12

13 (Deposition concluded at 2:47 p.m.)

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1 Whereupon, counsel was requested to give
2 instruction regarding the witness' review of
3 the transcript pursuant to the Civil Rules.

4

5 SIGNATURE:

6 Transcript review was requested pursuant to
7 the applicable Rules of Civil Procedure.

8

9 TRANSCRIPT DELIVERY:

10 Counsel was requested to give instruction
11 regarding delivery date of transcript.

12

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REPORTER'S CERTIFICATE

The State of Ohio,)
) SS:
County of Cuyahoga.)

I, Renee L. Pellegrino, a Notary Public within and for the State of Ohio, duly commissioned and qualified, do hereby certify that the within named witness, LEWIS COLOSIMO, was by me first duly sworn to testify the truth, the whole truth and nothing but the truth in the cause aforesaid; that the testimony then given by the above referenced witness was by me reduced to stenotypy in the presence of said witness; afterwards transcribed, and that the foregoing is a true and correct transcription of the testimony so given by the above referenced witness.

I do further certify that this deposition was taken at the time and place in the foregoing caption specified and was completed without adjournment.

1 I do further certify that I am not a
2 relative, counsel or attorney for either party,
3 or otherwise interested in the event of this
4 action.

5 IN WITNESS WHEREOF, I have hereunto set
6 my hand and affixed my seal of office at
7 Cleveland, Ohio, on this 19th day of March, 2021.
8
9

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11 
12

13 Renee L. Pellegrino, Notary Public
14 within and for the State of Ohio
15

16 My commission expires October 12, 2025.
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Veritext Legal Solutions
1100 Superior Ave
Suite 1820
Cleveland, Ohio 44114
Phone: 216-523-1313

March 19, 2021

To: ALLISON C. CARROLL

Case Name: National Prescription Opiate Litigation - Track 3 v.

Veritext Reference Number: 4486207

Witness: Lewis Colosimo Deposition Date: 3/15/2021

Dear Sir/Madam:

Enclosed please find a deposition transcript. Please have the witness review the transcript and note any changes or corrections on the included errata sheet, indicating the page, line number, change, and the reason for the change. Have the witness' signature notarized and forward the completed page(s) back to us at the Production address shown above, or email to production-midwest@veritext.com.

If the errata is not returned within thirty days of your receipt of this letter, the reading and signing will be deemed waived.

Sincerely,
Production Department

NO NOTARY REQUIRED IN CA

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DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4486207
CASE NAME: National Prescription Opiate Litigation - Track 3
DATE OF DEPOSITION: 3/15/2021
WITNESS' NAME: Lewis Colosimo

In accordance with the Rules of Civil
Procedure, I have read the entire transcript of
my testimony or it has been read to me.
I have made no changes to the testimony
as transcribed by the court reporter.

Date Lewis Colosimo
Sworn to and subscribed before me, a
Notary Public in and for the State and County,
the referenced witness did personally appear
and acknowledge that:

They have read the transcript;
They signed the foregoing Sworn
Statement; and
Their execution of this Statement is of
their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

DEPOSITION REVIEW
CERTIFICATION OF WITNESS

ASSIGNMENT REFERENCE NO: 4486207

CASE NAME: National Prescription Opiate Litigation - Track 3

DATE OF DEPOSITION: 3/15/2021

WITNESS' NAME: Lewis Colosimo

In accordance with the Rules of Civil Procedure, I have read the entire transcript of my testimony or it has been read to me.

I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s).

I request that these changes be entered as part of the record of my testimony.

I have executed the Errata Sheet, as well as this Certificate, and request and authorize that both be appended to the transcript of my testimony and be incorporated therein.

Date

Lewis Colosimo

Sworn to and subscribed before me, a Notary Public in and for the State and County, the referenced witness did personally appear and acknowledge that:

They have read the transcript;
They have listed all of their corrections in the appended Errata Sheet;
They signed the foregoing Sworn Statement; and
Their execution of this Statement is of their free act and deed.

I have affixed my name and official seal
this _____ day of _____, 20____.

Notary Public

Commission Expiration Date

ERRATA SHEET

VERITEXT LEGAL SOLUTIONS MIDWEST

ASSIGNMENT NO: 4486207

PAGE/LINE (S)	CHANGE	/REASON
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Date Lewis Colosimo

SUBSCRIBED AND SWORN TO BEFORE ME THIS

DAY OF _____, 20____.

Notary Public

Commission Expiration Date

[& - 19]

Page 1

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[190 - 4th]

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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